

General Information					
EudraVigilance Local Report Number	EU-EC-10008557015				
Sender Type	Regulatory authority				
Sender's Organisation	EEA Regulator				
Type of Report	Spontaneous				
Primary source country	European Economic Area				
Reporter's qualification	Healthcare Professional				
Case serious?	Yes				
Patient					
Age Group			Sex		
Adolescent			Male		
Reaction / Event					
MedDRA LLT	Duration	Outcome	Seriousness <sup>1</sup>		
Pulmonary embolism	0.0 Days	Fatal	death., hospital., other		
Cardiac arrest	0.0 Days	Fatal	death., hospital., other		
Drug Information					
Role <sup>2</sup>	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION - TOZINAMERAN		0.3 mL	Total	Not applicable
Drug Information (cont.)					
Info <sup>3</sup>	Drug	Indication	Pharm. Form	Route of Admin.	
	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION - TOZINAMERAN	Active immunization		Intramuscular	
Rechallenge matrix table					
Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?			
Cardiac arrest	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION - TOZINAMERAN	no - n/a			
Pulmonary embolism	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION - TOZINAMERAN	no - n/a			

<sup>1</sup> Seriousness: **death**=results in death; **life threat.**=life threatening; **hospital.**=requires hospitalization/prolongation of hospitalization; **disability**=results in disability/incapacity; **congen.**=congenital anomaly/birth defect; **other**=other medically important information; **(blank)**=non-serious

<sup>2</sup> Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

<sup>3</sup> Additional Information on Drug: **1**=Counterfeit; **2**= Overdose; **3**=Drug taken by the father; **4**=Drug taken beyond expiry date; **5**=Batch and lot tested and found within specifications; **6**=Batch and lot tested and found not within specifications; **7**=Medication error; **8**=Misuse; **9**=Abuse; **10**=Occupational exposure; **11**=Off label use; **(blank)** =no additional information