

General Information					
EudraVigilance Local Report Number	EU-EC-10009668305				
Sender Type	Health professional				
Sender's Organisation	NATIONAL AGENCY FOR THE SAFETY OF MEDICINE AND HEALTH PRODUCTS				
Type of Report	Spontaneous				
Primary source country	European Economic Area				
Reporter's qualification	Healthcare Professional				
Case serious?	Yes				
Patient					
Age Group			Sex		
Adolescent			Female		
Reaction / Event					
MedDRA LLT	Duration	Outcome	Seriousness <sup>1</sup>		
Cardiac arrest	1.0 Days	Fatal	death., life threat.		
Drug Information					
Role <sup>2</sup>	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN	1.0 Days	1.0 (DF)		Not applicable
Drug Information (cont.)					
Info <sup>3</sup>	Drug	Indication	Pharm. Form	Route of Admin.	
	COMIRNATY - TOZINAMERAN	COVID-19 vaccination		Intramuscular	
Rechallenge matrix table					
Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?			
Cardiac arrest	COMIRNATY - 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