EVPM ICSR(s)		Indivi	Individual Case Safety Report Form				EudraVigilance
Genera	al Information						
EudraVigilance Local Report Number		EU-E	EU-EC-10010811785				
Sender Type		Not a	Not available				
Sender's Organisation		Send	Senders Organisation is not displayed				
Type of Report		Spon	Spontaneous				
Primary source country		Europ	European Economic Area				
Reporter's qualification		Healt	Healthcare Professional				
Case serious?		Yes	Yes				
Patient							
Age Group			Age Group (as per reporter)				Sex
12-17 Years						Female	
Reactic	on / Event						
MedDRA LLT			Duration		Outcome		Seriousness ¹
Arrest cardiac			0.0 Days		Fatal		death.
Respiratory failure			0.0 Days		Fatal		death.
Drug In	formation						
Role ²	Drug		Duration	Dose		Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN			1.0 {DF}		Total	Not applicable
С	CLOPIDOGREL - CLOPIDOGREL, CLOPIDOGRE BESILATE						
С	- ACETYLSALICYLIC ACID						
С	- FERROUS (II) GLYCINE SULFATE COMPLEX						
С	- FLUTICASONE PROPIONATE, SALMETEROL						
С	- LANSOPRAZOLE						
Drug In	formation (cont.)						
Info ³	Drug		Indication		Pharm. Form		Route of Admin.
	COMIRNATY - TOZINAMERAN		SARS-CoV-2 vaccination		Concentrate for solution for injection		Dr Intramuscular use
	CLOPIDOGREL - CLOPIDOGREL, CLOPIDOGRE BESILATE - ACETYLSALICYLIC ACID - FERROUS (II) GLYCINE SULFATE COMPLEX - FLUTICASONE PROPIONATE, SALMETEROL		- N/A				
			N/A				
			N/A				
			N/A				
- LANSOPRAZOLE			N/A				

¹ 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

² Drug role: S=suspect; C=concomitant; I=interacting; N=not administered

³ 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