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	Age Group (as per reporter)	Sex
12-17 Years	Adolescent	Male

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Cardiac arrest	0.0 Days	Fatal	death., hospital., other
Pulmonary embolism	0.0 Days	Fatal	death., hospital., other

Drug Information

Role[2]	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
C	- METHYLPREDNISOLONE		16.0 mg	Days	Not applicable
C	- CICLOSPORIN		50.0 mg	Hours	Not applicable
C	- AZITHROMYCIN		500.0 mg	Weeks	Not applicable

Drug Information *(cont.)*

Info[3]	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION - TOZINAMERAN	Active immunization		Intramuscular use
	- METHYLPREDNISOLONE	N/A		Oral use
	- CICLOSPORIN	N/A		Oral use
	- AZITHROMYCIN	N/A		Oral use

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

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