

General Information	
EudraVigilance Local Report Number	EU-EC-10011110840
Sender Type	Health professional
Sender's Organisation	PFIZER S.R.L.
Type of Report	Spontaneous
Primary source country	Non-European Economic Area
Reporter's qualification	Healthcare Professional
Case serious?	Yes

Patient		
Age Group	Age Group (as per reporter)	Sex
12-17 Years		Female

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Oxygen saturation immeasurable		Fatal	death., hospital.
Postictal state		Fatal	death., hospital.
Breathing difficult		Fatal	death., hospital.
Cyanosis		Fatal	death., hospital.
Chest discomfort		Fatal	death., hospital.
Jugular vein distension		Fatal	death., hospital.
Crepitations		Fatal	death., hospital.
Bladder sphincter atony		Fatal	death., hospital.
Nervous system disorder		Fatal	death., hospital.
Involuntary movement (NOS)		Fatal	death., hospital.
Ventricular fibrillation		Fatal	death., hospital.
Syncope		Fatal	death., hospital.
Unequal pupils		Fatal	death., hospital.
Bradycardia		Fatal	death., hospital.
Heart arrest		Fatal	death., hospital.
Anal sphincter tone decreased		Fatal	death., hospital.
Cyanosis peripheral		Fatal	death., hospital.
Afebrile seizure		Fatal	death., hospital.

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	TOZINAMERAN - TOZINAMERAN	1.0 Days		Total	Not applicable

Drug Information (cont.)				
Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	TOZINAMERAN - TOZINAMERAN	COVID-19 immunisation		Intramuscular use

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