

General Information	
EudraVigilance Local Report Number	EU-EC-1001172923
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		Male

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Cardio-respiratory arrest		Fatal	death., hospital., other
Depressed level of consciousness		Unknown	other
Shock		Unknown	other
Renal disorder		Unknown	
Hypotension		Unknown	other
Loss of consciousness		Unknown	other
Ventricular fibrillation	0.0 Days	Recovered/Resolved	other
Liver disorder		Unknown	
Head injury		Unknown	
Non-occlusive mesenteric ischaemia		Fatal	death., other
Cardiac arrest		Fatal	death., life threat., hospital., other

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN			Total	Not applicable
C	- PARACETAMOL		200.0 mg		

Drug Information (cont.)				
Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN	COVID-19 immunisation		
	- PARACETAMOL	N/A		Oral 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

Report generated: 19/05/2024 01:50:02

Page 1 of 1