

General Information	
EudraVigilance Local Report Number	EU-EC-10010376118
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 <sup>1</sup>
Circulatory failure		Fatal	death., other
Myocardial infarction		Fatal	death., other
Stomach ulcer		Unknown	other
Lung edema		Unknown	other
Respiratory failure		Fatal	death., other
Gastric disorder		Unknown	
Stomach erosion		Unknown	other
Brain edema		Unknown	other
Brain herniation		Unknown	other
Lung congestion		Unknown	other
Myocardial bridging		Unknown	other

Drug Information					
Role <sup>2</sup>	Drug	Duration	Dose	Units in Interval	Action taken
S	TOZINAMERAN - TOZINAMERAN			Total	Not applicable

Drug Information (cont.)				
Info <sup>3</sup>	Drug	Indication	Pharm. Form	Route of Admin.
	TOZINAMERAN - TOZINAMERAN	COVID-19 immunisation		

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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

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