

General Information					
EudraVigilance Local Report Number	EU-EC-10007748750				
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	Age Group			Sex
	4 Years				Female
Reaction / Event					
MedDRA LLT	Duration	Outcome	Seriousness¹		
Flushed face		Unknown	other		
Red face		Unknown	other		
Blood pressure high		Unknown	other		
Tachycardia		Unknown	other		
Off label use		Unknown			
Felt faint		Unknown	other		
Vasomotor collapse	1.0 Days	Recovered/Resolved	other		
Drug administered to patient of inappropriate age		Unknown			
Tremor limb		Unknown	other		
Palpitations		Unknown	other		
Drug Information					
Role²	Drug	Duration	Dose	Units in Interval	Action taken
S	TOZINAMERAN - TOZINAMERAN	1.0 Days		Total	Not applicable
Drug Information (cont.)					
Info³	Drug	Indication	Pharm. Form	Route of Admin.	
	TOZINAMERAN - TOZINAMERAN	COVID-19 immunization			

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