

General Information					
EudraVigilance Local Report Number	EU-EC-10007970922				
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					
	<b>Age</b>	<b>Age Group</b>	<b>Sex</b>		
	0 Years		Male		
Reaction / Event					
<b>MedDRA LLT</b>	<b>Duration</b>	<b>Outcome</b>	<b>Seriousness<sup>1</sup></b>		
Myocarditis		Recovering/Resolving	hospital.		
Inappropriate age at vaccine administration		Unknown			
Drug Information					
<b>Role<sup>2</sup></b>	<b>Drug</b>	<b>Duration</b>	<b>Dose</b>	<b>Units in Interval</b>	<b>Action taken</b>
S	TOZINAMERAN - TOZINAMERAN	1.0 Days		Total	Not applicable
Drug Information (cont.)					
<b>Info<sup>3</sup></b>	<b>Drug</b>	<b>Indication</b>	<b>Pharm. Form</b>	<b>Route of Admin.</b>	
	TOZINAMERAN - TOZINAMERAN	COVID-19 immunisation			

<sup>1</sup> 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

<sup>2</sup> Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

<sup>3</sup> 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