TOZINAMERAN - TOZINAMERAN

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Individual Case Safety Report Form

General Information EudraVigilance Local Report Number EU-EC-10010893470 Health professional Sender Type Sender's Organisation PFIZER S.R.L. Type of Report Spontaneous Primary source country Non-European Economic Area Healthcare Professional Reporter's qualification Case serious? Yes **Patient Age Group** Sex Age Group (as per reporter) 3-11 Years Male Reaction / Event **MedDRA LLT Duration Outcome** Seriousness¹ Shortness of breath Unknown hospital. Acute chest pain Unknown hospital. Myopericarditis Unknown hospital. Drug Information Role² Drug **Duration** Dose **Units in Interval Action taken** 1.0 Days S TOZINAMERAN - TOZINAMERAN Total Not applicable Drug Information (cont.) Info³ Indication Pharm. Form Route of Admin.

COVID-19 immunisation

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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

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