

General Information

EudraVigilance Local Report Number

EU-EC-10011287208

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

12-17 Years

Age Group (as per reporter)

Sex

Male

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness <sup>1</sup>
Death		Fatal	death., other
Serum ferritin increased		Fatal	death., hospital.
Cyanosed	0.4166666666666663 Days	Fatal	death., hospital.
Shortness of breath	0.5 Days	Fatal	death., hospital.
Drug ineffective		Fatal	death., hospital.
Cytokine storm		Fatal	death., other
COVID-19		Fatal	death., hospital.
Oxygen saturation low	0.5 Days	Fatal	death., hospital.
Fever	0.5 Days	Fatal	death., hospital.
Tachypnea	0.5 Days	Fatal	death., hospital.
Fatigue	0.5 Days	Fatal	death., hospital.
Respiratory failure		Fatal	death., other
CRP increased		Fatal	death., hospital.
Fibrin D dimer high		Fatal	death., hospital., other
Cough		Fatal	death., hospital.
CT scan abnormal		Fatal	death., hospital.

Drug Information

Role <sup>2</sup>	Drug	Duration	Dose	Units in Interval	Action taken
S	TOZINAMERAN - TOZINAMERAN	1.0 Days		Total	Not applicable

Drug Information (cont.)

Info <sup>3</sup>	Drug	Indication	Pharm. Form	Route of Admin.
	TOZINAMERAN - TOZINAMERAN	COVID-19 immunisation		Intramuscular 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

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Page 1 of 1