

General Information

EudraVigilance Local Report Number

EU-EC-10009478826

Sender Type

Regulatory authority

Sender's Organisation

EEA Regulator

Type of Report

Spontaneous

Primary source country

European Economic Area

Reporter's qualification

Non-Healthcare Professional

Case serious?

Yes

Patient

Age Group

2 Months - 2 Years

Age Group (as per reporter)

Sex

Reaction / Event

MedDRA LLT

Fever

Duration

1.0 Days

Outcome

Recovered/Resolved

Seriousness¹

life threat.

Drug Information

Role²

S

Drug

COMIRNATY - TOZINAMERAN

Duration

Dose

Units in Interval

Action taken

Drug Information (cont.)

Info³

Drug

COMIRNATY - TOZINAMERAN

Indication

COVID-19 immunisation

Pharm. Form

Route of Admin.

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