Individual Case Safety Report Form

General Information

EudraVigilance Local Report Number	EU-EC-10011057758
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	Non-Healthcare Professional
Case serious?	Yes

Patient

Age Group	Age Group (as per reporter)	Sex
12-17 Years		Female

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Dizziness		Fatal	death.
Subdural haematoma		Fatal	death.
Subarachnoid haemorrhage		Fatal	death.
Aneurysm		Fatal	death.
Passed out		Fatal	death.
Headache		Fatal	death.
Vomiting		Fatal	death.
Cerebellar haemorrhage		Fatal	death.

Drug Information

Role[2]	Drug	Duration	Dose	Units in Interval	Action taken
S	TOZINAMERAN - TOZINAMERAN	1.0 Days		Total	Not applicable

Drug Information *(cont.)*

Info[3]	Drug	Indication	Pharm. Form	Route of Admin.
	TOZINAMERAN - TOZINAMERAN	COVID-19 immunisation		

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