Individual Case Safety Report Form

General Information

EudraVigilance Local Report Number	EU-EC-10008569158
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	Sex
	Male

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Vaccine exposure via breast milk		Fatal	death., hospital.
Failure to thrive		Fatal	death., hospital.
Diet refusal		Fatal	death., hospital.
Rash		Fatal	death., hospital.
Emotional distress		Fatal	death., hospital.
Pyrexia		Fatal	death., hospital.
Death		Fatal	death., hospital.
Thrombotic thrombocytopenic purpura		Fatal	death., hospital.
Hepatic enzyme increased		Fatal	death., hospital.

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		Transmammary

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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

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