Individual Case Safety Report Form

General Information

EudraVigilance Local Report Number	EU-EC-10012395920
Sender Type	Regulatory authority
Sender's Organisation	EEA Regulator
Type of Report	Spontaneous
Primary source country	European Economic Area
Reporter's qualification	Healthcare Professional
Case serious?	Yes

Patient

Age Group	Age Group (as per reporter)	Sex
65-85 Years		Female

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Bradycardia		Not Recovered/Not Resolved	hospital., other
Intracerebral hemorrhage	21.0 Days	Fatal	death., life threat., hospital.
Cardiac arrest		Recovered/Resolved	life threat., hospital., other
Hypernatremia		Unknown	hospital., other
Brain edema		Unknown	life threat., hospital.
Defecation difficult		Unknown	hospital., other
Death	0.0 Days	Fatal	death.
Hydrocephalus acquired		Unknown	life threat., hospital.
Consciousness decreased		Unknown	hospital., other
Unconscious		Unknown	hospital., other
Headache aggravated		Unknown	hospital., other

Drug Information

Role[2]	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN		1.0 {DF}		

Drug Information *(cont.)*

Info[3]	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - 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