

General Information	
EudraVigilance Local Report Number	EU-EC-10010660918
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	Age Group (as per reporter)	Sex
12-17 Years		Female

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Haemorrhage brain		Not Recovered/Not Resolved	life threat., hospital., disability, other
Unsteady gait		Not Recovered/Not Resolved	life threat., hospital., disability, other
Infarction		Not Recovered/Not Resolved	life threat., hospital., disability, other
Cerebral venous sinus thrombosis		Fatal	death., life threat., hospital., disability, other
Feeling unwell		Unknown	life threat., hospital., disability, other
Platelets decreased		Unknown	life threat., hospital., disability, other
Intracranial pressure increased		Unknown	life threat., hospital., disability, other
Weakness of arms		Unknown	life threat., hospital., disability, other
Cataract cortical		Unknown	life threat., hospital., disability, other
Vomiting		Unknown	life threat., hospital., disability, other
Muscle weakness right-sided		Unknown	life threat., hospital., disability, other
Thrombocytopenia		Unknown	life threat., hospital., disability, other

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

Drug Information (cont.)				
Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN	COVID-19 immunisation		

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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

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Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

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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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