

General Information	
EudraVigilance Local Report Number	EU-EC-10011108137
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 <sup>1</sup>
Anemia		Fatal	death.
Shortness of breath		Not Recovered/Not Resolved	hospital.
Seizure		Not Recovered/Not Resolved	hospital., other
Acute myocardial infarction		Fatal	death., other
Hemiparesis		Fatal	death., other
Bone marrow failure		Fatal	death., other
Dizziness		Not Recovered/Not Resolved	hospital.
Critical illness		Fatal	death., hospital., other
Red blood cell abnormality		Not Recovered/Not Resolved	life threat., hospital.
Hypoxia		Not Recovered/Not Resolved	life threat., hospital., other
Tiredness		Unknown	
Clot blood		Unknown	other
Fainting		Not Recovered/Not Resolved	hospital., other
Cardiogenic shock		Fatal	death., other
Pain in arm		Unknown	
Hemoglobin decreased		Not Recovered/Not Resolved	life threat., hospital.
Back pain		Unknown	
Body numbness		Not Recovered/Not Resolved	hospital.
Headache		Not Recovered/Not Resolved	hospital.
Somnolence		Not Recovered/Not Resolved	hospital.
Tingling		Not Recovered/Not Resolved	hospital.
Thrombotic thrombocytopenic purpura		Fatal	death., other

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

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

<sup>1</sup> 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

<sup>2</sup> Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

<sup>3</sup> 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