

General Information					
EudraVigilance Local Report Number	EU-EC-10007349293				
Sender Type	Regulatory authority				
Sender's Organisation	EEA Regulator				
Type of Report	Spontaneous				
Primary source country	European Economic Area				
Reporter's qualification	Non-Healthcare Professional				
Case serious?	No				
Patient					
Age		Age Group		Sex	
3 Years		Infant		Female	
Reaction / Event					
MedDRA LLT	Duration	Outcome	Seriousness ¹		
Seizure	0.0 Days	Not Recovered/Not Resolved			
Headache	0.0 Days	Not Recovered/Not Resolved			
Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN				
Drug Information (cont.)					
Info ³	Drug	Indication	Pharm. Form	Route of Admin.	
	COMIRNATY - TOZINAMERAN	COVID-19 prophylaxis		Intramuscular	

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