

General Information	
EudraVigilance Local Report Number	EU-EC-10009864895
Sender Type	Not available
Sender's Organisation	Senders Organisation is not displayed
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
12-17 Years		Male

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness <sup>1</sup>
Septic shock	26.0 Days	Fatal	death.

Drug Information					
Role <sup>2</sup>	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN		0.3 mL	Total	
C	- CLOBAZAM		20.0 mg		
C	- ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE		30.0 mg		
C	- SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE		450.0 mg		

Drug Information (cont.)				
Info <sup>3</sup>	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN	SARS-CoV-2 immunisation		Intramuscular use
	- CLOBAZAM	N/A		
	- ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	N/A		
	- SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE	N/A		

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

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