

General Information	
EudraVigilance Local Report Number	EU-EC-10010632312
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
12-17 Years	Adolescent	Male

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness <sup>1</sup>
Found dead		Fatal	death., life threat.
Fever		Fatal	death., life threat.
Headache		Fatal	death., life threat.
Appetite lost		Fatal	death., life threat.
Myocarditis		Fatal	death., life threat.

Drug Information					
Role <sup>2</sup>	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN		2.0 {DF}		

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

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

Report generated: 18/05/2024 20:28:00

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