

General Information	
EudraVigilance Local Report Number	EU-EC-10011358589
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
3-11 Years	Child	Male

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Cardio-respiratory arrest	1.0 Days	Fatal	death.
Myocarditis	1.0 Days	Fatal	death.

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN		0.2 mL		Not applicable
C	- BILASTINE			As Necessary	Not applicable

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

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: 15/05/2024 02:04:59

Page 1 of 1