

General Information	
EudraVigilance Local Report Number	EU-EC-10010375840
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?	Yes

Patient		
Age Group	Age Group (as per reporter)	Sex
0-1 Month		Female

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness <sup>1</sup>
Axillary lymph nodes enlarged		Not Recovered/Not Resolved	life threat., other
Breast swelling		Not Recovered/Not Resolved	life threat., other
Asthmatic crisis	1.0 Days	Recovering/Resolving	life threat., other
Fever		Not Recovered/Not Resolved	life threat., other

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

Drug Information (cont.)				
Info <sup>3</sup>	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN	N/A		Intramuscular use

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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