

General Information					
EudraVigilance Local Report Number	EU-EC-10007343114				
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					
	<b>Age</b>	<b>Age Group</b>	<b>Sex</b>		
	3 Years	Infant	Female		
Reaction / Event					
<b>MedDRA LLT</b>	<b>Duration</b>	<b>Outcome</b>	<b>Seriousness<sup>1</sup></b>		
Increased blood pressure	11.0 Days	Not Recovered/Not Resolved			
Peripheral circulatory failure	11.0 Days	Not Recovered/Not Resolved			
Nerve pain	11.0 Days	Not Recovered/Not Resolved			
Dizziness	11.0 Days	Not Recovered/Not Resolved			
Nausea	5.0 Days	Not Recovered/Not Resolved			
Giddiness	11.0 Days	Not Recovered/Not Resolved			
Taste metallic	11.0 Days	Not Recovered/Not Resolved			
Muscle twitching	16.0 Days	Not Recovered/Not Resolved			
Pruritus	16.0 Days	Not Recovered/Not Resolved			
Insomnia	8.0 Days	Not Recovered/Not Resolved			
Tachycardia	8.0 Days	Not Recovered/Not Resolved			
Breath shortness	11.0 Days	Not Recovered/Not Resolved			
Throat tightness	16.0 Days	Not Recovered/Not Resolved			
Vaccination site pain	16.0 Days	Not Recovered/Not Resolved			
Drug Information					
<b>Role<sup>2</sup></b>	<b>Drug</b>	<b>Duration</b>	<b>Dose</b>	<b>Units in Interval</b>	<b>Action taken</b>
S	COMIRNATY - TOZINAMERAN				
Drug Information (cont.)					
<b>Info<sup>3</sup></b>	<b>Drug</b>	<b>Indication</b>	<b>Pharm. Form</b>	<b>Route of Admin.</b>	
	COMIRNATY - TOZINAMERAN	COVID-19 immunization		Intramuscular	

<sup>1</sup> 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

<sup>2</sup> Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

<sup>3</sup> 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