

General Information	
EudraVigilance Local Report Number	EU-EC-10010224444
Sender Type	Health professional
Sender's Organisation	PFIZER S.R.L.
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
	Neonate	Male

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Exposure during pregnancy		Fatal	death.
Brain damage		Fatal	death.
Birth asphyxia		Fatal	death.
Premature birth		Unknown	other

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN	1.0 Days		Total	Not applicable

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

Information Concerning the Parent for a Parent-Child/Foetus Report

Parent	
Age	Sex

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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Page 1 of 1