Individual Case Safety Report Form

General Information

EudraVigilance Local Report Number	EU-EC-10011103759
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	Child	Male

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Unconsciousness		Recovered/Resolved	life threat.
QT interval prolonged		Unknown	other
Vomiting		Unknown	
Cardio-respiratory arrest		Recovered/Resolved	life threat.
Hypoxic brain damage		Fatal	death., life threat.
Headache		Unknown	
Pyrexia		Unknown	
Injection site pain		Unknown	

Drug Information

Role[2]	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN		1.0 {DF}	Total	
S	KAFTRIO - TEZACAFTOR, ELEXACAFTOR, IVACAFTOR	4.0 Days			

Drug Information *(cont.)*

Info[3]	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN	COVID-19 immunisation		
	KAFTRIO - TEZACAFTOR, ELEXACAFTOR, IVACAFTOR	N/A		

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