EVPM ICSR(s) Individual Case Safety Report Form						EudraVigilanc	
General Information							
EudraVigilance Local Report Number		EU-E	EU-EC-10010893528				
Sender Type		Healt	Health professional				
Sender's Organisation		PFIZI	ER S.R.L.				
Type of Report		Spon	Spontaneous				
Primary source country		Non-	Non-European Economic Area				
Reporter's qualification		Healt	Healthcare Professional				
Case serious?		Yes	Yes				
Patient							
Age Group			Age Group (as per reporter)			Sex	
3-11 Years							Male
Reaction / Event							
MedDR	IDRA LLT		Duration Outcom			ome	Seriousness ¹
Adult product administered to child			Un		Unkn	iown	
Headache			Unknow			iown	
Fever			Unknown				
Acute chest pain				Unknown			
Myocarditis				Unknown		-	other
Frontal headache			Unknown		-		
Chest pain			Unknown				
Fatigue Pericarditis			Unknowr Unknowr		-	other	
			UTIKHOWIT				
Role ²	nformation Drug		Duration	Dose		Units in Interval	Action taken
S S	TOZINAMERAN - TOZINAMERAN		1.0 Days	Dose		Total	Not applicable
			1.0 Days				
Info ³	nformation (cont.)		Indication			Pharm, Form	Route of Admin.
1110-	TOZINAMERAN - TOZINAMERAN		COVID-19 immunisa			Fildrini. FOFM	Route of Admin.
TOZINAMENAN - TOZINAMERAN							

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
Drug role: S=curpact: C=concenticat: N=other administered

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