Individual Case Safety Report Form

EVPINI ICSR(S)			ndividual Case Safety Report Form				Eudravigilance
General Information							
EudraVigilance Local Report Number		EU-E	EU-EC-10013023257				
Sender Type		Regul	Regulatory authority				
Sender's Organisation		EEA F	EEA Regulator				
Type of Report			Spontaneous				
Primary source country			European Economic Area				
Reporter's qualification			Healthcare Professional				
Case serious?		Yes	Yes				
Patient							
Age Group			Age Group (as per reporter)			Sex	
18-64 Years						Male	
Reaction / Event							
MedDRA LLT			Duration		Outcome		Seriousness ¹
Death			Fatal			death., hospital., other	
Drug In	nformation						
Role ²	Drug		Duration	Dose	U	Jnits in Interval	Action taken
S	COMIRNATY - TOZINAMERAN						
С	- OXCARBAZEPINE						
Drug In	formation (cont.)						
Info ³	Drug		Indication		PI	harm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN		N/A				
	OXCARBAZEPINE		Epileptic seiz				

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

 $^{2 \}quad \text{Drug role: } \textbf{S} \text{=} \text{suspect; } \textbf{C} \text{=} \text{concomitant; } \textbf{I} \text{=} \text{interacting; } \textbf{N} \text{=} \text{not administered}$

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