Individual Case Safety Report Form

General Information

EudraVigilance Local Report Number	EU-EC-10014990829
Sender Type	Health professional
Sender's Organisation	EUDRAVIGILANCE WEB TRADER
Type of Report	Spontaneous
Primary source country	Non-European Economic Area
Reporter's qualification	Healthcare Professional
Case serious?	Yes

Patient

Age Group	Age Group (as per reporter)	Sex
65-85 Years		

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Hyperkalaemia		Fatal	death., other
Blood pressure decreased		Fatal	death.
2019 novel coronavirus infection		Recovered/Resolved	
Hepatic function disorder		Fatal	death.

Drug Information

Role[2]	Drug	Duration	Dose	Units in Interval	Action taken
S	EVRENZO - ROXADUSTAT		150.0 mg		Unknown
S	VEKLURY - REMDESIVIR				Unknown

Drug Information (cont.)

Info[3]	Drug	Indication	Pharm. Form	Route of Admin.
	EVRENZO - ROXADUSTAT	Drug use for unknown indication	Tablet	
	VEKLURY - REMDESIVIR	2019 novel coronavirus infection		

Rechallenge matrix table

Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?
Blood pressure decreased	EVRENZO - ROXADUSTAT	no - n/a
Hepatic function disorder	EVRENZO - ROXADUSTAT	no - n/a
Hyperkalaemia	EVRENZO - ROXADUSTAT	no - 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