

General Information	
EudraVigilance Local Report Number	EU-EC-10013023013
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
65-85 Years		Female

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Oxygen saturation decreased	4.0 Days	Fatal	death., hospital., other
Oedema	4.0 Days	Fatal	death., hospital., other
Fluid retention	4.0 Days	Fatal	death., hospital., other
Death	0.0 Days	Fatal	death.

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN				
C	CLOPIDOGREL - CLOPIDOGREL, CLOPIDOGREL BESILATE				
C	INSULIN DEGLUDEC - INSULIN DEGLUDEC				
C	LIRAGLUTIDE - LIRAGLUTIDE				
C	XULTOPHY - LIRAGLUTIDE, INSULIN DEGLUDEC				
C	- AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL				
C	- AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE				
C	- CLOPIDOGREL, CLOPIDOGREL BESILATE				
C	- METFORMIN HYDROCHLORIDE				
C	- METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP				
C	- PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE				
C	- PRAVASTATIN SODIUM				
C	- PRAVASTATIN, PRAVASTATIN SODIUM				

Drug Information (cont.)				
Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN	N/A		
	CLOPIDOGREL - CLOPIDOGREL, CLOPIDOGREL BESILATE	N/A		
	INSULIN DEGLUDEC - INSULIN DEGLUDEC	N/A		
	LIRAGLUTIDE - LIRAGLUTIDE	N/A		
	XULTOPHY - LIRAGLUTIDE, INSULIN DEGLUDEC	N/A		
	- AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL	N/A		
	- AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE	N/A		
	- CLOPIDOGREL, CLOPIDOGREL BESILATE	N/A		
	- METFORMIN HYDROCHLORIDE	N/A		
	- METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP	N/A		
	- PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE	N/A		
	- PRAVASTATIN SODIUM	N/A		
	- PRAVASTATIN, PRAVASTATIN SODIUM	N/A		

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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

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Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

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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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