

General Information					
EudraVigilance Local Report Number	EU-EC-10009643379				
Sender Type	Health professional				
Sender's Organisation	NATIONAL AGENCY FOR THE SAFETY OF MEDICINE AND HEALTH PRODUCTS				
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	
More than 85 Years	Elderly			Female	
Reaction / Event					
MedDRA LLT	Duration		Outcome		Seriousness¹
Cardio-respiratory arrest			Fatal		death.
Sudden death			Fatal		death.
Drug Information					
Role²	Drug	Duration	Dose	Units in Interval	Action taken
S	JCOVDEN - COVID-19 VACCINE JANSSEN (AD26.COV2.S)	1.0 Days	1.0 {DF}	Total	Not applicable
Drug Information (cont.)					
Info³	Drug	Indication	Pharm. Form	Route of Admin.	
	JCOVDEN - COVID-19 VACCINE JANSSEN (AD26.COV2.S)	COVID-19 vaccination		Intramuscular use	

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