

General Information

EudraVigilance Local Report Number	EU-EC-10011221257
Sender Type	Pharmaceutical company
Sender's Organisation	JANSSEN CILAG INTERNATIONAL
Type of Report	Spontaneous
Primary source country	Non-European Economic Area
Reporter's qualification	Non-Healthcare Professional
Case serious?	Yes

Patient

Age Group	Age Group (as per reporter)	Sex
12-17 Years	Adolescent	Male

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness ¹
Product administered to patient of inappropriate age		Unknown	death.
Off label use		Unknown	death.
Streptococcal sore throat		Fatal	death.

Drug Information

Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	COVID-19 VACCINE JANSSEN (AD26.COV2.S) - COVID-19 VACCINE JANSSEN (AD26.COV2.S)			Total	Not applicable

Drug Information (cont.)

Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	COVID-19 VACCINE JANSSEN (AD26.COV2.S) - COVID-19 VACCINE JANSSEN (AD26.COV2.S)	Prophylactic vaccination	Suspension for injection	Unknown

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

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Page 1 of 1