

| General Information | |
|------------------------------------|-----------------------------|
| EudraVigilance Local Report Number | EU-EC-10011323051 |
| 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 |
| Clot blood | | Unknown | death., other |
| Death | | Fatal | death., other |
| Product administered to patient of inappropriate age | | Unknown | death., other |
| Off label use | | Unknown | death., other |
| Heart disorder | | Unknown | death., other |

| 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 |

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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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