

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-10008246334	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Capillary leak syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Distributive shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	[AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TERBUTALINE] (C - n/a - n/a - [n/a - n/a - n/a]), [THEOPHYLLINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008195117	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008197653	05/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Atrial fibrillation (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral embolism (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008164806	01/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	COVID-19 (n/a - Unknown - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008152972	31/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008135660	30/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008138926	30/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abdominal pain upper (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death), Ear pain (n/a - Unknown - Results in Death), Fatigue (n/a - Unknown - Results in Death), Headache (n/a - Unknown - Results in Death), Pain in extremity (n/a - Unknown - Results in Death), Pallor (n/a - Unknown - Results in Death), Pre-existing condition improved (n/a - Unknown - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR