

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)	Suspected/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-1000840280	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - 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-10008490499	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - 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])	PIOGLITAZONE [PIOGLITAZONE] (C - Type 2 diabetes mellitus - n/a - [n/a - 30mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral]), [BUMETANIDE] (C - Peripheral swelling - n/a - [n/a - 1mg - Oral]), [BUMETANIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Essential hypertension - n/a - [30d - 40mg - Oral]), [METFORMIN HYDROCHLORIDE, GLIPIZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008492328	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Back pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Fatal - Results in Death, Life Threatening, 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-10008492391	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - 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])	[FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10008492415	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening), Pneumonia (n/a - Unknown - Results in Death, Life Threatening), Pulmonary embolism (n/a - Unknown - Results in Death, Life Threatening), Thrombosis (n/a - Fatal - Results in Death, Life Threatening)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	METHOTREXATE [METHOTREXATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDRALAZINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROXYCHLOROQUINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10008492669	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Thrombosis (n/a - Unknown - 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-10008492675	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Cerebrovascular accident (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])	IRON [IRON] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10008492676	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - 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-10008492730	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - 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-10008492885	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Intensive care (n/a - Fatal - Results in Death), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - 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])	MELATONIN [MELATONIN] (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Oral]), XARELTO [RIVAROXABAN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral]), [AMIODARONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 100mg - Oral]), [CALCIPOTRIOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Topical]), [CARVEDILOL] (C - Blood pressure abnormal - n/a - [n/a - 5mg - Oral]), [COLECALCIFEROL] (C - Vitamin supplementation - n/a - [n/a - 25ug - Oral]), [CYANOCOBALAMIN, VITAMIN B12] (C - Vitamin supplementation - n/a - [n/a - 100ug - Oral]), [FISH OIL] (C - Nutritional supplementation - n/a - [n/a - 1000mg - Oral]), [FORMOTEROL FUMARATE, GLYCOPYRRONIUM, BUDESONIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GLIPIZIDE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]), [GLYCERYL TRINITRATE] (C - Chest pain - n/a - [n/a - 4mg - Oral]), [LEVOSALBUTAMOL] (C - Dyspnoea - n/a - [n/a - n/a]), [LIDOCAINE, LIDOCAINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Other]), [LOPERAMIDE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 2mg - Oral]), [LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 25mg - Oral]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 4mg - Oral]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10meq - Oral]), [ROPINIROLE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 2mg - Oral]), [ROPINIROLE, ROPINIROLE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Oral]), [SALBUTAMOL SULFATE] (C - Dyspnoea - n/a - [n/a - 3mL - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [THIOCTIC ACID] (C - Product used for unknown indication - n/a - [n/a - 200mg - Oral]), [TORASEMIDE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral])	ICSR
EU-EC-10008492933	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Male	No	Adverse reaction (n/a - Unknown - Results in Death), Death (n/a - Fatal - 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-10008492977	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - 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-10008493867	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Cardiac arrest (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Not Recovered/Not Resolved - 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])	EMTRICITABINE, TENOFOVIR ALAFENAMIDE, RILPIVIRINE [EMTRICITABINE, TENOFOVIR ALAFENAMIDE, RILPIVIRINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), METHOTREXATE [METHOTREXATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CEFEPIRIME] (C - Product used for unknown indication - n/a - [n/a - 2g - Unknown]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 600mg - Unknown]), [GLIPIZIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Unknown]), [HYDROMORPHONE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 2mg - Unknown]), [INSULIN, INSULIN HUMAN] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [MIRTAZAPINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NITROFURANTOIN] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown])	ICSR
EU-EC-10008493881	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - 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])	[ACETYSALICYLIC ACID, ASPIRIN BP] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10008494042	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - 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-10008494053	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Tremor (n/a - Unknown - 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-10008494607	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Unknown - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - 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-10008494983	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dizziness (n/a - Unknown - Results in Death, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Results in Death, Other Medically Important Condition), Hypertension (3d - Recovered/Resolved - Results in Death, Other Medically Important Condition), Vomiting (n/a - Unknown - 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-10008497978	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Asthenia (n/a - Unknown - Results in Death), Confusional state (n/a - Not Recovered/Not Resolved - Results in Death), Death (n/a - Fatal - Results in Death), Heart rate increased (n/a - Unknown - Results in Death), Influenza like illness (n/a - Unknown - Results in Death), Respiratory rate increased (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-10008497970	29/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Acute respiratory failure (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Enccephalopathy (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory acidosis (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, 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-10008479984	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Cerebrovascular accident (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - 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-10008480202	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gait inability (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Impaired driving ability (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mechanical ventilation (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 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
										Muscle spasms (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)			
EU-EC-10008481288	28/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Bradycardia (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), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemodialysis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Liver function test increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Transfusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008463647	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 (n/a - Unknown - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Foaming at mouth (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008482223	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008464363	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008464652	28/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008464653	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Back pain (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Epistaxis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Haemoptysis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Increased viscosity of upper respiratory secretion (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Secretion discharge (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008468700	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008486667	27/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death), Haemorrhagic stroke (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	[LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008441557	26/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Not Specified	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008441930	26/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008411791	23/04/2021	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.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	[AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL 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-10008413601	23/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (0d - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008402410	22/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008387135	21/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Thrombosis (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008382855	21/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008356558	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Cardiac failure (n/a - Unknown - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pain (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008354029	18/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Not Specified	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	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.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.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.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.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.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.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.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.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.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.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.CO.V2.S) [COVID-19 VACCINE JANSSEN (AD26.CO.V2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR