





EU Local Number	EV Category	Report Type	Primary Qualification	Primary Reference	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List PT (Duration / Outcome - Seriousness Criteria)	Supplementing 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	
									Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest X-ray abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computed tomography thorax abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Continuous positive airway pressure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Long infiltration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 not positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)		[DOLYCODONE HYDROCHLORIDE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TRAMACLOLONE ACETONIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		
EU-EC-1009746603	2008/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Male	No	Suspected COVID-19 (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (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-100974147	19/08/2021	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), Fatigue (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Unknown - Results in Death, Other Medically Important Condition), Haemorrhage (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-100974250	19/08/2021	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, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dependence on respirator (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - 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-100974188	18/08/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Influenza like illness (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-100974958	18/08/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Male	No	Cardiovascular accident (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), Stupor (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-100974961	18/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Dyspareunia (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Injection site pain (n/a - Fatal - Results in Death), Pulse abnormal (n/a - Fatal - Results in Death), Pyrexia (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])	FLUTICASONI PROPIONATE, SALMETEROL FLUTICASONI PROPIONATE, SALMETEROL XINAFOATE (C - Asthma - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-100972324	18/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Female	No	Acute kidney injury (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Autopsy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epstein-Barr virus infection (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneucystitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (n/a - Fatal - 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-100970618	17/08/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Male	No	Blood pressure decreased (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Results in Death, Caused/Prolonged Hospitalisation), Unrelaxable event (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-100970708	17/08/2021	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), Suspected COVID-19 (n/a - Unknown - 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-1009711421	17/08/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (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-100969123	16/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death), Dyspareunia (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Pain (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-100968455	14/08/2021	Spontaneous	Non-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 COV2 S) (COVID-19 VACCINE, JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-100967519	13/08/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chills (174 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Fatigue (174 - Fatal - Results in Death), Headache (174 - Fatal - Results in Death), Malaise (174 - Fatal - Results in Death), Myalgia (174 - Fatal - Results in Death), Nausea (174 - Fatal - Results in Death), Pyrexia (174 - 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-100967468	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Acute kidney injury (n/a - Fatal - Results in Death), Cerebral haematomas (n/a - Fatal - Results in Death), Cerebral haemorrhage (n/a - Fatal - Results in Death), Coagulopathy (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Haemorrhage (n/a - Fatal - Results in Death), Hepatic failure (n/a - Fatal - Results in Death), Hypovolaemic shock (n/a - Fatal - Results in Death), Mesenteric vein thrombosis (n/a - Fatal - Results in Death), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Pneumothorax (n/a - Fatal - Results in Death), Portal vein thrombosis (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death), Renal infarct (n/a - Fatal - Results in Death), Renal vein thrombosis (n/a - Fatal - Results in Death), Shock (n/a - Fatal - Results in Death), Splenic infarction (n/a - Fatal - Results in Death), Splenic vein thrombosis (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death), Venous occlusion (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])	MANITOL [MANITOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [ALBUMIN, HUMAN ALBUMIN SOLUTION, HUMAN PLASMA PROTEINS WITH NOT LESS THAN 90% ALBUMIN, HUMAN SERUM ALBUMIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [AMOXICILLIN, AMOXICILLIN SODIUM, AMOXICILLIN TRIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [ATRAZOLAM, ATRAZOLAM BESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ATROPINE, ATROPINE SULFATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [CARMELOSE SODIUM, GELATIN, PECTIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [CEFOTAXIME, CEFOTAXIME SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [DOLUSTIN SULFATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [DOBUTAMINE, DOBUTAMINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ENLAPRIL, ENLAPRIL MALEATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [EZETIMIBE] (C - n/a - Unknown - [n/a - n/a - n/a]), [GLUCOSE, GLUCOSE, ANHYDROUS] (C - n/a - Unknown - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - n/a - Unknown - [n/a - n/a - n/a]), [IODIXANOL, IODIXANOL IODINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - Unknown - [n/a - n/a - n/a]), [LUCICANE, LUCICANE HYDROCHLORIDE MONOHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [MAGNESIUM CHLORIDE HEXAHYDRATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, GLUCOSE MONOHYDRATE, SODIUM ACETATE TRIHYDRATE, SODIUM GLUCONATE, MAGNESIUM CHLORIDE HEXAHYDRATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM ACETATE TRIHYDRATE, SODIUM GLUCONATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [MICRONISED SPIRONOLACTONE, POTASSIUM CAURENDATE, SPIRONOLACTONE, SPIRONOLACTONE BP] (C - n/a - Unknown - [n/a - n/a - n/a]), [NORADRENALINE TARTRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [NISTATIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [PROPRANOLOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [RIFAMPICIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [SEVOFLURANE] (C - n/a - Unknown - [n/a - n/a - n/a]), [SUFENTANIL, SUFENTANIL CITRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [TOBRAMYCIN, TOBRAMYCIN SULFATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [TRANEXAMIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-100967372	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cerebral haemorrhage (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Headache (1d - 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 - n/a])	Not reported	ICSR
EU-EC-100967105	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Nervous system disorder (1d - Fatal - Results in Death) Death (n/a - Fatal - Results in Death, Life Threatening, 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 - n/a])	[BENFOTIAMINE, CYANOCOBALAMIN, BENFOTIAMINE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - 1), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - 1), [POTASSIUM CHLORIDE] (C - n/a - n/a - 1), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - n/a - n/a - 1)	ICSR
EU-EC-100966030	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (3d - 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 - n/a])	[BIPERIDEN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 2]DF) (n/a), [CLONAZEPAM] (C - n/a - Unknown - [n/a - 3]DF) (n/a), [ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PIRAPERONE, PIRAPERONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 2]DF) (n/a)	ICSR
EU-EC-100966407	12/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Male	No	Brain death (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Monoparesis (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Phosbotonia (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Tetralocular pain (n/a - Recovering/Resolving - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - 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-1009645281	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 90 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-100964649	06/08/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	No	Cardiac disorder (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death), Medication error (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 AVAILABLE (BNT 162) (S - Immunisation - n/a - [n/a - n/a - Unknown]), NOT AVAILABLE (BNT 162) (S - Immunisation - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-1009617119	06/08/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Female	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-1009597480	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Headache (n/a - Unknown - 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-100960408	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Gonzalez C, Marmouze N. COVID-19 vaccine-induced myocarditis: Case report with literature review, Diabetes Lamp, Metabolic Syndrome Clinical Research & Reviews.	65-85 Years	Elderly	Female	No	Acute renal incompetence (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Unknown - 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-1009604934	05/08/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - 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-1009597412	04/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombosis (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-1009597373	04/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Female	No	Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (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-100958095	04/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Female	No	Cardiac arrest (n/a - Fatal - Results in Death), Cardiovascular accident (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death), Right ventricular failure (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])	[DOCAUSATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1009515396	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	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])	Not reported	ICSR
EU-EC-1009522201	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Asplenia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Mastitis (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-1009440357	27/07/2021	Spontaneous	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, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - 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), Gait disturbance (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 Local Number	EV Category Report Date	Report Type	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age (in years)	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
									Guillain-Barre syndrome (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-1000946339	23/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Male	No	COVID-19 VACCINE JANSSEN (AD26 COV2 S) [COVID-19 VACCINE JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	FDN OX [C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]]	CSR
EU-EC-1000841296	22/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	COVID-19 VACCINE JANSSEN (AD26 COV2 S) [COVID-19 VACCINE JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	AMLODIPINE, AMLODIPINE MALEATE [C - n/a - Unknown - [n/a - 10mg - Oral]], HYDROCHLOROTHIAZIDE, BISOPROLOL HEMIFUMARATE [C - n/a - Unknown - [n/a - 10mg - Oral]], DRAZEPAM [C - n/a - Unknown - [n/a - 10mg - Oral]]	CSR
EU-EC-1000841219	21/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	COVID-19 VACCINE (AD26 COV2 S (RECOMBINANT)) JANSSEN (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000941794	20/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Male	No	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	CSR
EU-EC-1000941906	20/07/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 pneumonia (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dependence on respirator (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	Not reported	CSR
EU-EC-1000943331	19/07/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	COVID-19 VACCINE (AD26 COV2 S (RECOMBINANT)) JANSSEN (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000936536	16/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	CSR
									Syncope (n/a - Unknown - Results in Death, Other Medically Important Condition), Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bpity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac valve vegetation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chemotherapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cholelithiasis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Compensated longarm abdomen (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Compensated longarm abdomen (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Compensated longarm thorax abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Critical illness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Echoardiogram (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Echoardiogram abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Electrocardiogram (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic mass (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intracardiac mass (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Liposarcoma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oliguria (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ovarian vein thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pancreatitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Platelet transfusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Scan with contrast (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Turgor decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death)	COVID-19 VACCINE (AD26 COV2 S (RECOMBINANT)) JANSSEN (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), [ATORVASTATIN] (C - Coronary artery disease - Dose not changed - [n/a - 10mg - Oral]), [METFORMIN] (C - Type 2 diabetes mellitus - Dose not changed - [n/a - 500mg - Oral]), [SUETAPINE] (C - Insomnia - Dose not changed - [n/a - 25mg - Oral]), [SPRONOLACTONE] (C - Essential hypertension - Dose not changed - [n/a - 25mg - Oral])	CSR	
EU-EC-10009361743	14/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 VACCINE (AD26 COV2 S (RECOMBINANT)) JANSSEN (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	[AMLODIPINE, INDAPAMIDE, PERINDOPRIL] (C - Essential hypertension - Dose not changed - [n/a - n/a - Oral]), [ATORVASTATIN] (C - Coronary artery disease - Dose not changed - [n/a - 10mg - Oral]), [METFORMIN] (C - Type 2 diabetes mellitus - Dose not changed - [n/a - 500mg - Oral]), [SUETAPINE] (C - Insomnia - Dose not changed - [n/a - 25mg - Oral]), [SPRONOLACTONE] (C - Essential hypertension - Dose not changed - [n/a - 25mg - Oral])	CSR
EU-EC-1000936362	13/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Not Specified	No	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	CSR
									Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cardiovascular accident (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Injury (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Petchchie (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Transient ischaemic attack (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling)	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	CSR
EU-EC-1000936868	12/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	CSR
									Acute respiratory failure (n/a - Fatal - Results in Death), Atrial fibrillation (n/a - Fatal - Results in Death), COVID-19 pneumonia (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Nucleic acid test (n/a - Fatal - Results in Death), Obesity (n/a - Fatal - Results in Death), Polymerase chain reaction (n/a - Fatal - Results in Death), Pulmonary embolism (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	CSR
EU-EC-1000936871	12/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Female	No	COVID-19 VACCINE JANSSEN (AD26 COV2 S) [COVID-19 VACCINE JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	ELIGUS [PAXIBAN] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [DVAJZ PEGIFERONE, FESOTERODINE, FUMARAAT] (C - Product used for unknown indication - n/a - [n/a - 4mg - Unknown]), [ACETYL SALICYLIC ACID, ASPIRIN 80] (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]), [AMMONIUM, AMMONIUM HYDROXIDE] (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]), [ASCORBIC ACID, RETACAROTENE, BOTIN, CALCIUM PANTOTHENATE, COLECAL, FERROL, CYANOCOBALAMIN, FOLIC ACID, NICOTINAMIDE, THAMINE NITRATE, POTASSIUM CHLORIDE, ZINC OXIDE, CHROMIUM CHLORIDE, CLUPRIC OXIDE, FERROUS FUMARATE, MAGNESIUM OXIDE, MANGANESE SULFATE, POTASSIUM IODIDE, PYRIDOXINE HYDROCHLORIDE, SODIUM MXYBATE, CALCIUM HYDROGEN PHOSPHATE, SODIUM BILELATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BUPROPION HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 300mg - Unknown]), [DOCAUATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 250mg - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 600mg - Unknown]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown]), [MIRTAZAPINE] (C - Product used for unknown indication - n/a - [n/a - 7.5mg - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SMVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [TROTROPUM] (C - Product used for unknown indication - n/a - [n/a - 18mg - Unknown])	CSR
									Apical syndrome (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Aphasia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Quasiparalysed limb motion (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Back pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Compensated longarm (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Constipation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dialysis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Discomfort (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dyskinesia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dystasia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Electroencephalogram (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Fine motor skill dysfunction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal tube insertion (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Noninfective encephalitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Renal function test abnormal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Sleep disorder (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Stroke (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), 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), Polymerase chain reaction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Compensated longarm head abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Continuous haemofiltration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic steatosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung assist device therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mental impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pericardial swelling (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Right ventricular dysfunction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombectomy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Withdrawal of the support (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])	[AMTRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - Unknown]), [SMVASTATIN] (C - n/a - n/a - [n/a - Unknown]), [TERBUTALINE] (C - Capillary leak syndrome - n/a - [n/a - n/a - Unknown]), [THEOPHYLLINE] (C - Capillary leak syndrome - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000936246	06/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Female	No	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	CSR
									Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Compensated longarm head abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Continuous haemofiltration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic steatosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung assist device therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mental impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pericardial swelling (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Right ventricular dysfunction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombectomy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Withdrawal of the support (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	CSR
EU-EC-1000936723	06/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 VACCINE (AD26 COV2 S (RECOMBINANT)) JANSSEN (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000928629	07/07/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	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	CSR
									Dependence on respirator (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Phlebotomy (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Centrovacular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Compensated longarm (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Magnetic resonance imaging (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), X-ray (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])	ELIGUS [PAXIBAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUICARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ATORVASTATIN] (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]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PAROXETINE, PAROXETINE HYDROCHLORIDE, PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000928619	07/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	CSR
									Asthma (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), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sarcoidosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heart decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Abdominal discomfort (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Abdominal distension (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (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	CSR







EU Local Number	EV Category	Report Type	Primary Source Qualification	Primary Source Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Parent Drug 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-1000846070	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		65-85 Years	Elderly	Female	No	Thrombosis (via - Fatal - Results in Death) Laboratory test (via - Fatal - Results in Death) Thrombosis (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])	LISINAPRIL, LISINAPRIL OXYDRATE (C - Blood pressure measurement - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000845335	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Male	No	Thrombocytopenia (via - 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 - [via - n/a - Unknown])		ICSR
EU-EC-1000847866	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Female	No	Death (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000840392	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Female	No	Death (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000841452	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		Not Specified	Adult	Female	No	Cardiovascular accident (via - Unknown - Results in Death, Other Medically Important Condition), Death (via - 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 - [via - n/a - Unknown])		ICSR
EU-EC-1000849492	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		65-85 Years	Elderly	Male	No	Acute kidney injury (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anticoagulant therapy (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest tube insertion (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Encephalopathy (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mechanical ventilation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Peripheral ischaemia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal replacement therapy (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Shock (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombocytopenia (via - 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 - [via - n/a - Unknown])		ICSR
EU-EC-1000848495	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Male	No	Cardiac arrest (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000848495	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		Not Specified	Adult	Female	No	Death (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000847840	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		65-85 Years	Elderly	Male	No	Acute coronary syndrome (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute respiratory distress syndrome (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Alcohol use (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Central venous catheterisation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypothermia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Life support (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulseless electrical activity (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic shock (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Substance use (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Supraventricular tachycardia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Toxicologic test abnormal (via - 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 - [via - n/a - Unknown])		ICSR
EU-EC-1000843397	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Male	No	Unresponsive to stimuli (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anticoagulant therapy (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Autopsy (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (via - 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 - [via - n/a - Unknown])		ICSR
EU-EC-1000841865	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Female	No	Death (via - Fatal - Results in Death), Thrombosis (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000841894	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		65-85 Years	Elderly	Male	No	Acute myocardial infarction (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anticoagulant therapy (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Arrhythmia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blurred positive pressure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blood magnesium normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardioversion (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Catheterisation cardiac (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest X-ray normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coronary artery disease (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coronary artery occlusion (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ejection fraction decreased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Electrocardiogram ST segment depression (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Full blood count (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haematocrit decreased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemoglobin decreased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Left ventricular dysfunction (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mean cell volume decreased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Metabolic function test normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain in jaw (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulse absent (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), QRS axis abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Rate (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Red blood cell count decreased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Resuscitation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Topoxon increased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vascular graft occlusion (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vascular graft thrombosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ventricular tachycardia (via - 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 - [via - n/a - Unknown])	PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), ACEYLSALICYLIC ACID, ASPIRIN (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), AMLODIPINE, AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [via - 40mg - Unknown]), HYDROXYCARBAMIDE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), LISINAPRIL, LISINAPRIL ANHYDROUS, LISINAPRIL OXYDRATE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), METOPROLOL, SUCCINATE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), MORPHINE, MORPHINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [via - 2mg - Unknown]), OMEPRAZOLE, OMEPRAZOLE MAGNESIUM (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000869893	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Female	No	Computerised tomogram thorax abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pleural effusion (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (via - 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 - [via - n/a - Unknown])		ICSR
EU-EC-1000870373	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Male	No	Anticoagulant therapy (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (via - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hypocoagulation (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Mechanical ventilation (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Transcatheter pacing (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])	PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), ACEYLSALICYLIC ACID, ASPIRIN (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), ATORVASTATIN (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), BUPROPION HYDROCHLORIDE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), CARVEDILOL (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), FLUCLOXACIN, FLUCLOXETINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), FUROSEMIDE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), HYDROCHLORIDE, BITARTATE, PARACETAMOL (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), SPIRONOLACTONE (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000870492	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		Not Specified	Adult	Male	No	Death (via - Fatal - Results in Death), Pleural fluid decreased (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000870328	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		65-85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Intracardiac thrombus (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (via - 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 - [via - n/a - Unknown])	BUPROPION (C - n/a - n/a - [via - n/a - Unknown]), CARVEDILOL (C - n/a - n/a - [via - n/a - Unknown]), DOXAZOSIN, DOXAZOSIN MESILATE (C - n/a - n/a - [via - n/a - Unknown]), FUROSEMIDE, FUROSEMIDE SODIUM (C - n/a - n/a - [via - n/a - Unknown]), HYDRAZINE (C - n/a - n/a - [via - n/a - Unknown]), OLMESARTAN MEDOXOMIL (C - n/a - n/a - [via - n/a - Unknown]), ROBUVASTATIN, ROBUVASTATIN CALCIUM (C - n/a - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000870353	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Male	No	Catheter site erythema (via - Fatal - Results in Death), Catheter site swelling (via - Fatal - Results in Death), Catheter site warmth (via - Fatal - Results in Death), Central venous catheter removal (via - Fatal - Results in Death), Central venous catheterisation (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000869814	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		65-85 Years	Elderly	Female	No	Coronary angioplasty (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Dyspepsia (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000869559	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Female	No	Intracardiac thrombus (via - Fatal - Results in Death), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Resuscitation (via - 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 - [via - n/a - Unknown])		ICSR
EU-EC-1000869590	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		65-85 Years	Elderly	Female	No	Asthma (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Decreased appetite (via - Fatal - Results in Death), Dyspnoea (via - Fatal - Results in Death), Hoarseness (via - Fatal - Results in Death), Myocardial infarction (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])	CLOPIDOGREL HYDROGEN SULFATE (CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), IRON (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), ATORVASTATIN CALCIUM (C - Product used for unknown indication - n/a - [via - 20mg - Unknown]), INSULIN, INSULIN HUMAN (C - Diabetes mellitus - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000867349	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		Not Specified	Adult	Male	No	Cardiovascular accident (via - Unknown - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Inappropriate schedule of product administration (via - 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 - [via - n/a - Unknown])		ICSR
EU-EC-1000867542	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		Not Specified	Adult	Female	No	Death (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000867239	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		More than 65 Years	Elderly	Female	No	Cardiac failure (via - Unknown - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (via - Unknown - Results in Death, Other Medically Important Condition), Pneumothorax (via - Unknown - Results in Death, Other Medically Important Condition), Pulmonary oedema (via - Unknown - Results in Death, Other Medically Important Condition), Renal impairment (via - 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 - [via - 5ml - Intramuscular])		ICSR
EU-EC-1000864608	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		Not Specified	Adult	Female	No	Death (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000864835	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available		18-64 Years	Adult	Female	No	Death (via - Fatal - Results in Death)	COVID-19 VACCINE, JANSSEN (AD26 COV2 S) [COVID-19 VACCINE, JANSSEN (AD26 COV2 S)] (S - Immunisation - Not applicable - [via - n/a - Unknown])		ICSR
EU-EC-1000864811	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available		65-85 Years	Elderly	Female	No	Clostridium difficile colitis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Clostridium test positive (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Colitis ischaemic (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Deep vein thrombosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxemia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Jugular vein thrombosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulseless electrical activity (via - 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 - [via - n/a - Unknown])	CYMBALTA (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), TREBIA (INSULIN DEGLUCIDE) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), ACEYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), FLUTICASON, FLUTICASON PROPIONATE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), ISABAPTIN (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), HYDROXYCARBAMIDE (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), HYDROCHLORIDE, BITARTATE, PARACETAMOL (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), INSULIN ASPART (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR



EU Local Number	EV Category Date	Report Type	Primary Source Qualification	Primary Source Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex	Patient Race	Reaction List PT (Duration / Outcome - Seriousness Criteria)	Superseding 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-100264814	14/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Resuscitation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Subdural vein thrombosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombophlebitis superficial (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthma (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Autoregulation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Feeling hot (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Impaired work ability (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ischaemia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Peripheral swelling (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Poor peripheral circulation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary oedema (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulse absent (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (via - 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 (via - via - Unknown))	[LISINAPRIL, LISINAPRIL ANHYDROUS, LISINAPRIL DIIHYDRATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - via - [via - via - Unknown]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [ISMARSTATIN] (C - Product used for unknown indication - via - [via - via - Unknown]), [LANTANOLAN GLUCONATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - via - [via - via - Unknown]), [LISINAPRIL, LISINAPRIL DIIHYDRATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Diabetes mellitus - via - [via - via - Unknown])	CSR
EU-EC-1000637914	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Elderly	Female	Asthma (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebrovascular accident (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Computed tomogram head abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heart rate increased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (via - 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 (via - via - Unknown))	Not reported	CSR
EU-EC-100063829	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Adult	Male	Death (via - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable (via - via - Unknown))	Not reported	CSR
EU-EC-1000627135	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	Cerebrovascular accident (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - 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 (via - via - Unknown))	Not reported	CSR
EU-EC-1000627410	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	Aphasia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blindness (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebrovascular accident (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dysphagia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hemiparesis (via - 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 (via - via - Unknown))	Not reported	CSR
EU-EC-100063804	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	Death (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Mechanical ventilation (via - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Suspected COVID-19 (via - Unknown - 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 (via - via - Unknown))	Not reported	CSR
EU-EC-1000611204	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	Death (via - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable (via - via - Unknown))	Not reported	CSR
EU-EC-1000611306	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	Death (via - 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 (via - via - Unknown))	Not reported	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Arteriosclerosis (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable (via - via - Unknown))	Not reported	CSR
EU-EC-1000611319	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Acute kidney injury (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute respiratory failure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diabetic hypokalaemia coma (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaria (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Shock (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (via - 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 (via - via - Unknown))	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - via - [via - via - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - via - [via - via - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - via - [via - via - Unknown])	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	Chest X-ray (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Computed tomogram head abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Edema (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic vein thrombosis (via - 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 (via - via - Unknown))	[FERROUS SULFATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [IMEPRAZOLE] (C - Product used for unknown indication - via - [via - via - Unknown])	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Elderly	Male	Acute myocardial infarction (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Balance disorder (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bradycardia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coronary artery disease (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Essential hypertension (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), High fracture (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypokalaemia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaria (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malnutrition (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), X-ray of pelvis and hip abnormal (via - 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 (via - via - Unknown))	[ALFUZOSIN] (C - Product used for unknown indication - via - [via - via - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - via - [via - via - Unknown]), [ATROPINE, ATROPINE SULFATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [DIPHENHYDRAMINE] (C - Product used for unknown indication - via - [via - via - Unknown]), [HYDROCODONE] (C - Product used for unknown indication - via - [via - via - Unknown]), [LISINAPRIL, LISINAPRIL DIIHYDRATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [METOPROLOL, METOPROLOL TARTARATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - via - [via - via - Unknown]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - via - [via - via - Unknown])	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	Abdominal pain (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Adrenal haemorrhage (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computed tomogram abdomen abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computed tomogram head abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dependence on respirator (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarhoea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Life support (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaria (via - Recovered/Resolved - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Surgery (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (via - Fatal - 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 (via - via - Unknown))	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - via - via - [via - via - via]), [GLIPZIDE] (C - via - via - [via - via - via]), [INSULIN GLARGINE] (C - via - via - [via - via - via]), [LEVOTHYROXINE SODIUM] (C - via - via - [via - via - via]), [LISINAPRIL, LISINAPRIL DIIHYDRATE] (C - via - via - [via - via - via]), [METOPROLOL, METOPROLOL TARTARATE] (C - Product used for unknown indication - via - [via - via - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - via - [via - via - Unknown]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - via - via - [via - via - via])	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	Death (via - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable (via - via - Unknown))	Not reported	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Death (via - Fatal - Results in Death), Pulmonary thrombosis (via - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable (via - via - Unknown))	Not reported	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	Asthma (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebrovascular accident (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Computed tomogram head abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarhoea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Muscle spasms (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (via - 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 (via - via - Unknown))	[ALENDRONATE SODIUM, ALENDRONATE SODIUM TRIHYDRATE, ALENDRONIC ACID] (C - Product used for unknown indication - via - [via - 70mg - Unknown]), [ALLOPURINOL] (C - Product used for unknown indication - via - [via - 100mg - Unknown]), [CINACROSALAMINE] (C - Product used for unknown indication - via - [via - 10mg - Unknown]), [PARACETAMOL] (C - Par - via - [via - 325mg - Unknown]), [PARACETAMOL] (C - Pyram - via - [via - via - via]), [THIAMINE HYDROCHLORIDE] (C - Product used for unknown indication - via - [via - via - Unknown])	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	Blood glucose increased (via - Fatal - Results in Death), Cerebrovascular accident (via - Fatal - Results in Death), Computed tomogram head normal (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Dysphagia (via - Fatal - Results in Death), Gastrointestinal tube insertion (via - Fatal - Results in Death), Neurological symptom (via - Fatal - Results in Death), Surgery (via - Fatal - Results in Death), Thrombosis (via - Fatal - Results in Death), Unresponsive to stimuli (via - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable (via - via - Unknown))	Not reported	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Activated partial thromboplastin time normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anticoagulant therapy (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Computed tomogram head (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fibrin D dimer normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Generalized tonic-clonic seizure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Influenza A virus test negative (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Influenza B virus test (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), International normalized ratio normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Normal prothrombin brain natriuretic peptide increased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Platelet count normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia aspiration (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory syncytial virus test negative (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (via - 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 (via - via - Unknown))	[ELIQUIS (APIXBAN) (C - Pulmonary embolism - via - [via - 50mg - via]), [MELNITON (MELNITON)] (C - Product used for unknown indication - via - [via - 50mg - via]), [SOLICALFEROL] (C - Product used for unknown indication - via - [via - 50mg - via]), [FURIFEROL] (C - Product used for unknown indication - via - [via - 200mg - via]), [LISINAPRIL, LISINAPRIL DIIHYDRATE] (C - Product used for unknown indication - via - [via - 10mg - via]), [METOPROLOL, METOPROLOL TARTARATE] (C - Product used for unknown indication - via - [via - 100mg - via]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - via - via - [via - via - via]), [MODAFINIL] (C - Product used for unknown indication - via - [via - 100mg - Unknown]), [DIETHEPINE, GUETHAPINE FUMARATE] (C - Product used for unknown indication - via - [via - 50mg - via]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - via - [via - 100mg - via]), [VALPROIC ACID] (C - Secure - via - [via - 1000mg - Unknown])	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	Status epilepticus (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Abdominal pain (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute kidney injury (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computed tomogram abdomen (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dialysis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electroencephalogram abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic steatosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Magnetic resonance imaging head normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pelvic venous thrombosis (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ultrasound Doppler abnormal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ultrasound abdomen normal (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (via - Fatal - 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 (via - via - Unknown))	[CYMBALTA (DULOXETINE, DULOXETINE HYDROCHLORIDE)] (C - Product used for unknown indication - via - [via - via - Unknown]), [DEFERASIROX (DEFERASIROX)] (C - Product used for unknown indication - via - [via - via - Unknown]), [PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SEQUIHYDRATE)] (C - Product used for unknown indication - via - [via - via - Unknown]), [INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - via - [via - via - Transdermal]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - via - [via - via - Unknown]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - via - [via - via - Unknown]), [ISMARSTATIN] (C - Product used for unknown indication - via - [via - via - Unknown])	CSR
EU-EC-1000611317	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	Death (via - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable (via - via - Unknown))	Not reported	CSR
EU-EC-1000611317	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	Brain edema (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Coronary artery stenosis (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Central disorder (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Central thrombosis (via - 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 (via - via - Unknown))	[L.Y.SINE] (C - Product used for unknown indication - via - [via - 1000mg - Unknown]), [OLEA EUROPAEA LEAF] (C - Product used for unknown indication - via - [via - 750mg - Unknown])	CSR



EU Local Number	EV Entry Date	Report Type	Primary Qualification	Primary Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List PT (Duration / Outcome - Seriousness Criteria)	Supplementing 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-1008611480	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Cerebrovascular accident (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Mental impairment (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)			ICSR
EU-EC-100851896	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	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 - Intramuscular])		ICSR
EU-EC-100849286	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	Brain stem syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			ICSR
EU-EC-100849459	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	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])		ICSR
EU-EC-100849231	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	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])		ICSR
EU-EC-100849245	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening), Phonemia (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 MESILATE, 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]) HYDRAZINE (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])		ICSR
EU-EC-100849275	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	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])		ICSR
EU-EC-100849276	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	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])		ICSR
EU-EC-100849270	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	Cerebrovascular accident (n/a - Not Recovered/Not Resolved - 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])		ICSR
EU-EC-100849285	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	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 - Intramuscular]) BUDESONIDE, GLYCOPYRRONUM BROMIDE, FORMOTEROL FUMARATE DIBYDRATE (BUDESONIDE, GLYCOPYRRONUM BROMIDE, FORMOTEROL FUMARATE DIBYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) MELNITOLAN, MELNITOLAN (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]) 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]) CALCIPTROLOL (C - Product used for unknown indication - n/a - [n/a - n/a - Topical]) CARVEDILOL (C - Blood pressure abnormal - n/a - [n/a - 5mg - Oral]) DOLECALCEROL (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]) GULPIZIDE (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]) GLYCERYL TRINERATE (C - Chest pain - n/a - [n/a - 4mg - Oral]) LEVOSALBUTAMOL (C - Dyspnoea - n/a - [n/a - n/a - Inhalation]) LIDOCANE, LIDOCANE 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]) OXANDEFTRON, OXANDEFTRON HYDROCHLORIDE, OXANDEFTRON HYDROCHLORIDE DIBYDRATE (C - Product used for unknown indication - n/a - [n/a - 4mg - Oral]) POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]) ROPINROLE, ROPINROLE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 2mg - Oral]) ROPINROLE, ROPINROLE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 1mg - Oral]) SALBUTAMOL, SULFATE (C - Dyspnoea - n/a - [n/a - 3ml - Inhalation]) SALBUTAMOL, SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - Inhalation]) 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-100849293	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Male	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])		ICSR
EU-EC-100849297	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	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])		ICSR
EU-EC-100849387	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	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]) METHOTREXATE (METHOTREXATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) DEFERIPYRINE (C - Product used for unknown indication - n/a - [75g - Unknown]) ISABAPTIN (C - Product used for unknown indication - n/a - [n/a - 600mg - Unknown]) GULPIZIDE (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 - Inhalation]) NINTÉZANNE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) RIFORQUANTON (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]) ACETYLSALICYLIC ACID, ASPIRIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		ICSR
EU-EC-100849381	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	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 - Intramuscular])		ICSR
EU-EC-100849442	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	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])		ICSR
EU-EC-100849453	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Male	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])		ICSR
EU-EC-100849467	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	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])		ICSR
EU-EC-100849483	30/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	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 (SD - 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])		ICSR
EU-EC-100849778	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Asthma (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])		ICSR
EU-EC-100849790	29/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	Acute respiratory failure (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Antralgia (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), Encephalopathy (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 - Intramuscular])		ICSR
EU-EC-100849894	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	Cerebrovascular accident (n/a - Fatal - 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])		ICSR
EU-EC-100849302	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Thrombosis (n/a - Fatal - Results in Death), Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gait instability (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), Muscle spasms (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombosis (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])		ICSR
EU-EC-100849128	29/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), 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), Hypertension (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), Seeps (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tetanus (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])		ICSR
EU-EC-100849367	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	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 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])		ICSR
EU-EC-100849423	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	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])		ICSR
EU-EC-1008494363	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Female	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])		ICSR
EU-EC-100849462	28/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	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])		ICSR
EU-EC-100849463	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	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), Serrator dysfunction (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Thrombotic (n/a - Not Recovered/Not Resolved - 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])		ICSR
EU-EC-100849687	27/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	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])		ICSR
EU-EC-100841557	26/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Not Specified	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])		ICSR
EU-EC-100841930	26/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	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])		ICSR
EU-EC-100841901	23/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Death (SD - 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])		ICSR
EU-EC-1008387135	21/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	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])		ICSR
EU-EC-100838225	21/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	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 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])		ICSR
EU-EC-100838558	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	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 COV2 S) (COVID-19 VACCINE JANSSEN (AD26 COV2 S)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])		ICSR
EU-EC-1008385429	18/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Not Specified	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])		ICSR
EU-EC-1008195117	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	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])		ICSR
EU-EC-100819763	05/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	Anal fistula (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), Hypertension (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])		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 report)	Patient Sex	Patient Detail Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Supporting/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-10008164806	01/04/2021	Spontaneous	Not Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	No	Peripheral embolism (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition) COVID-19 (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE_JANSENEN (AZD1225C) [S] COVID-19 VACCINE_JANSENEN (AZD1225C) [S] - Immunisation - Not applicable - (n/a - n/a - Unknown)	Not reported	ICSR
EU-EC-10008152972	31/03/2021	Spontaneous	Not 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_JANSENEN (AZD1225C) [S] COVID-19 VACCINE_JANSENEN (AZD1225C) [S] - Immunisation - Not applicable - (n/a - n/a - Unknown)	Not reported	ICSR
EU-EC-10008136660	30/03/2021	Spontaneous	Not Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE_JANSENEN (AZD1225C) [S] COVID-19 VACCINE_JANSENEN (AZD1225C) [S] - Immunisation - Not applicable - (n/a - n/a - Unknown)	Not reported	ICSR
EU-EC-10008138826	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), Pain in extremity (n/a - Unknown - Results in Death), Pain in extremity (n/a - Unknown - Results in Death), Pain in extremity (n/a - Unknown - Results in Death), Pre-existing condition improved (n/a - Unknown - Results in Death)	COVID-19 VACCINE_JANSENEN (AZD1225C) [S] COVID-19 VACCINE_JANSENEN (AZD1225C) [S] - Immunisation - Not applicable - (n/a - n/a - Unknown)	Not reported	ICSR