COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date:	20-Jan-2022
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All UK spontaneous reports received up to and Áncluding FJ/0F/202G for COVID-19 vaccines where Athe brand has not been specified.

A report of a suspected ADR to the Yellow CardÁscheme does not necessarily mean that it was caused by the vaccine, only that theÁeporter has a suspicion it may have. Underlying or previously undiagnosedÁllness unrelated to vaccination can also be factors in such reports. The relativeÁnumber and nature of reports should therefore not be used to compare the safety ofÁhe different vaccines. All reports are kept under continual review in order toÁdentify possible new risks.

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Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Iron deficiency anaemia	1	0
Anaemias NEC		
Anaemia	3	0
Coagulopathies		
Disseminated intravascular coagulation	1	0
Eosinophilic disorders		
Eosinophilia	1	0
Haematological disorders		
Blood disorder	1	1
Leukocytoses NEC		
Hyperleukocytosis	1	0
Lymphatic system disorders NEC		
Lymph node pain	4	0
Lymphadenitis	1	0
Lymphadenopathy	32	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	0
Myelosuppression	1	0
Neutropenias		
Neutropenia	1	0
Platelet disorders NEC		
Platelet disorder	1	0
Thrombocytopenias		
Immune thrombocytopenia	5	3
Thrombocytopenia	9	0
Blood disorders SOC TOTAL	63	4

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Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac conduction disorders		
Atrioventricular block	1	0
Bundle branch block	1	0
Cardiac disorders NEC		
Cardiac disorder	1	0
Cardiac signs and symptoms NEC		
Cardiac discomfort	2	0
Palpitations	33	0
Heart failures NEC		
Cardiac failure	1	0
Ischaemic coronary artery disorders		
Acute myocardial infarction	1	0
Angina pectoris	6	0
Myocardial infarction	9	3
Myocardial disorders NEC		
Left ventricular dilatation	1	0
Left ventricular dysfunction	1	0
Myocardial injury	1	0
Noninfectious myocarditis		
Immune-mediated myocarditis	1	0
Myocarditis	2	0
Noninfectious pericarditis		
Pericarditis	4	0
Rate and rhythm disorders NEC		
Bradycardia	1	0
Cardiac flutter	3	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	8	0
Supraventricular arrhythmias		
Atrial fibrillation	4	0
Atrial tachycardia	1	0
Supraventricular tachycardia	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	2	1
Cardiac disorders SOC TOTAL	86	4

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Reaction Name	Total	Fatal
Congenital disorders		
Cardiac disorders congenital NEC		
Heart disease congenital	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	2	0
Ear disorder	1	0
Ear pain	9	0
Ear swelling	1	0
Eustachian tube disorders		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	1	0
External ear disorders NEC		
Excessive cerumen production	2	0
Hearing losses		
Deafness	5	0
Deafness unilateral	1	0
Hypoacusis	4	0
Hyperacusia		
Hyperacusis	1	0
Inner ear disorders NEC		
Vestibular disorder	1	0
Inner ear signs and symptoms		
Tinnitus	24	0
Vertigo	15	0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	69	0

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Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Thyroiditis	1	0
Female gonadal function disorders		
Ovulation delayed	1	0
Thyroid hyperfunction disorders		
Thyrotoxic crisis	1	0
Endocrine disorders SOC TOTAL	3	0

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leaction Name	Total	Fata
ve disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	5	
Corneal infections, oedemas and inflammations		
Keratitis	1	
Iris and uveal tract infections, irritations and inflammations		
Iridocyclitis	1	
Lacrimation disorders		
Dry eye	2	
Lacrimation increased	2	
Lid, lash and lacrimal infections, irritations and inflammations		
Chalazion	1	
Eyelid cyst	1	
Eyelid margin crusting	1	
Swelling of eyelid	1	
Ocular disorders NEC		
Eye disorder	4	
Eye pain	6	
Eye swelling	8	
Ocular discomfort	1	
Periorbital swelling	3	
Ocular infections, inflammations and associated manifestations		
Eye allergy	1	
Eye pruritus	3	
Ocular sensation disorders		
Photophobia	4	
Pupil disorders		
Pupil fixed	1	
Pupils unequal	1	
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal haemorrhage	1	
Retinal vein occlusion	2	
Retinal structural change, deposit and degeneration	_	
Macular degeneration	1	
Retinal toxicity	1	
Visual disorders NEC		
Diplopia	5	
Photopsia	2	
Vision blurred	12	
	12	
Visual impairment and blindness (excl colour blindness)		
Blindness Blindness transient	4	
	1	
Visual impairment ve disorders SOC TOTAL	5 81	

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eaction Name	Total	Fata
astrointestinal disorders		
Anal and rectal pains		
Proctalgia	1	
Colitis (excl infective)		
Colitis	2	
Colitis ulcerative	1	
Crohn's disease	1	
Dental pain and sensation disorders		
Toothache	3	
Diarrhoea (excl infective)		
Diarrhoea	52	
Dyspeptic signs and symptoms		
Dyspepsia	3	
Faecal abnormalities NEC		
Abnormal faeces	2	
Faeces discoloured	3	
Flatulence, bloating and distension		
Abdominal distension	4	
Flatulence	1	
Gastritis (excl infective)		
Gastritis	1	
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	11	
Abdominal pain lower	3	
Abdominal pain lower Abdominal pain upper	27	
Abdominal tenderness	21	
	2	
Gastrointestinal pain	2	
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	4	
Gastrooesophageal reflux disease	3	
Gastrointestinal signs and symptoms NEC	45	
Abdominal discomfort	15	
Dysphagia	2	
Gastrointestinal spastic and hypermotility disorders		
Irritable bowel syndrome	2	
Gastrointestinal stenosis and obstruction NEC		
lleus	1	
Gastrointestinal vascular occlusion and infarction		
Mesenteric vein thrombosis	1	
Gingival disorders, signs and symptoms NEC		
Gingival pain	2	
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoids	1	
Intestinal haemorrhages		
Intestinal haemorrhage	1	
Nausea and vomiting symptoms		
Nausea	138	
Retching	3	
Vomiting	58	
Vomiting projectile	2	
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	1	
Haematemesis	1	
Oral dryness and saliva altered		

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Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Dry mouth	1	0
Oral soft tissue disorders NEC		
Oral papule	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	1	0
Lip exfoliation	1	0
Oral pain	1	0
Paraesthesia oral	1	0
Oral soft tissue swelling and oedema		
Lip swelling	8	0
Mouth swelling	1	0
Stomatitis and ulceration		
Aphthous ulcer	1	0
Mouth ulceration	3	0
Tongue disorders		
Glossitis	1	0
Tongue signs and symptoms		
Glossodynia	2	0
Swollen tongue	2	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	378	1

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site erythema	1	0
Application and instillation site reactions		
Application site swelling	1	0
Asthenic conditions		
Asthenia	43	0
Chronic fatigue syndrome	1	0
Fatigue	205	
Malaise	85	0
Body temperature altered		
Hyperthermia	1	0
Hypothermia	1	0
Death and sudden death		
Death	12	12
Sudden death	1	1
Febrile disorders		
Pyrexia	164	0
Feelings and sensations NEC		
Chills	106	0
Feeling abnormal	24	0
Feeling cold	23	0
Feeling hot	13	0
Feeling of body temperature change	10	0
Sensation of foreign body	1	0
Thirst	5	0
Gait disturbances		
Gait disturbance	8	0
Gait inability	2	0
General signs and symptoms NEC		
Condition aggravated	8	0
Crying	2	0
General physical health deterioration	3	0
Illness	29	0
Influenza like illness	36	0
Local reaction	1	0
Peripheral swelling	38	0
Secretion discharge	1	0
Swelling	27	0
Swelling face	14	0
Symptom recurrence	1	0
Unevaluable event	1	0
Inflammations		
Inflammation	7	0
Systemic inflammatory response syndrome	1	0
Injection site reactions		
Injection site discomfort	1	l o
Injection site erythema	3	C
Injection site inflammation	2	
Injection site mass	6	
Injection site pain	11	-
Injection site pruritus	1	0
Injection site reaction	1	
Injection site swelling	3	

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Reaction Name General disorders General disorders cont'd	Total	Fatal
Injection site warmth	1	
Interactions		
	1	
Drug interaction Mass conditions NEC		
	2	
Cyst Mass	2	
Nodule	1	
Oedema NEC		
Oedema peripheral	1	
Pain and discomfort NEC		
Axillary pain	11	
Chest discomfort	7	
Chest pain	35	
Discomfort	6	
Facial discomfort	1	
Facial pain	4	
Pain	91	
Tenderness	1	
Therapeutic and nontherapeutic responses		
Adverse drug reaction	4	
Adverse reaction	1	
Drug ineffective	4	
Drug intolerance	1	
No reaction on previous exposure to drug	1	
Surgical failure	1	
Therapeutic product effect decreased	1	
Therapeutic product ineffective	1	
Therapeutic response decreased	1	
Therapeutic response unexpected	1	
Vaccination site reactions		
Vaccination site bruising	2	
Vaccination site erythema	17	
Vaccination site hypoaesthesia	1	
Vaccination site induration	2	
Vaccination site inflammation	2	
Vaccination site mass	4	
Vaccination site movement impairment	1	
Vaccination site pain	15	
Vaccination site papule	1	
Vaccination site pruritus	3	
Vaccination site rash	2	
Vaccination site reaction	1	
Vaccination site scab	1	
Vaccination site swelling	12	
Vaccination site warmth	6	
eneral disorders SOC TOTAL	1153	

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Reaction Name	Total	Fatal
Hepatic disorders		
Cholecystitis and cholelithiasis		
Cholecystitis acute	1	0
Cholestasis and jaundice		
Jaundice	1	0
Hepatic vascular disorders		
Portal vein thrombosis	3	0
Hepatic disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Immune system disorders		
Acute and chronic sarcoidosis		
Sarcoidosis	1	0
Allergic conditions NEC		
Hypersensitivity	6	0
Allergies to foods, food additives, drugs and other chemicals		
Allergy to vaccine	3	0
Drug hypersensitivity	3	0
Food allergy	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	2	0
Atopic disorders		
Seasonal allergy	1	0
Immune and associated conditions NEC		
Bacille Calmette-Guerin scar reactivation	1	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Transplant rejections		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	20	0

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Reaction Name Total Fatal Infections Abdominal and gastrointestinal infections Appendicitis 0 **Bacterial infections NEC** Arthritis bacterial 0 0 Cellulitis 2 Breast infections 0 Mastitis Caliciviral infections Norovirus infection 0 1 Candida infections 0 Candida infection Central nervous system and spinal infections Encephalitis 0 1 0 Meningitis aseptic Clostridia infections Clostridium difficile infection 0 Coronavirus infections COVID-19 29 0 Suspected COVID-19 0 Eye and eyelid infections 0 Eve infection 0 Hordeolum Fungal infections NEC 0 **Fungal infection** 1 Herpes viral infections Disseminated varicella zoster vaccine virus infection 0 0 Genital herpes 2 13 0 Herpes zoster Herpes zoster oticus 0 1 Oral herpes 0 4 Infections NEC Abscess 0 Infection 9 0 Localised infection 0 1 Infectious transmissions Vaccine virus shedding 0 Influenza viral infections Influenza 21 0 Lower respiratory tract and lung infections Lower respiratory tract infection 3 1 Pneumonia 11 3 Mumps viral infections 0 Mumps 1 Sepsis, bacteraemia, viraemia and fungaemia NEC 0 Sepsis 2 Skin structures and soft tissue infections 0 Rash pustular 1 Staphylococcal infections Furuncle 2 0 Trypanosomal infections 0 African trypanosomiasis 1 Upper respiratory tract infections Laryngitis 0

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Reaction Name Total Fatal Infections cont'd Infections 9 0 Nasopharyngitis Sinusitis 0 1 0 Tonsillitis 2 Urinary tract infections 0 Kidney infection 2 Urinary tract infection 0 4 Viral infections NEC 0 Gastroenteritis viral 1 0 Sweating fever 1 Viral infection 0 2 Infections SOC TOTAL 141 4

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Reaction Name	Total	Fatal
njuries		
Abdominal and gastrointestinal injuries NEC		
Gallbladder injury	1	
Bone and joint injuries NEC		
Joint injury	1	
Cerebral injuries NEC		
Subdural haematoma	1	
Exposures associated with pregnancy, delivery and lactation		
Exposure via breast milk	1	
Maternal exposure during breast feeding	1	
Maternal exposure during pregnancy	(
Exposures to agents or circumstances NEC		
Exposure to vaccinated person	2	
Eye injuries NEC		
Eye contusion	1	
Eye injury	3	
Intentional product misuses		
Intentional product misuse	2	
Intentional product use issues		
Intentional dose omission	2	
Medication errors, product use errors and issues NEC		
Medication error	2	
Prescription drug used without a prescription	1	
Vaccination error	1	
Wrong technique in product usage process	2	
Muscle, tendon and ligament injuries		
Muscle strain	1	
Tendon rupture	1	
Nerve injuries NEC		
Nerve injury	1	
Non-site specific injuries NEC		
Fall	11	
Non-site specific procedural complications		
Incision site pain	1	
Injection related reaction	2	
Off label uses		
Off label use	1	
Overdoses NEC		
Overdose	1	
Product administration errors and issues		
Expired product administered	2	
Inappropriate schedule of product administration	2	
Incorrect route of product administration	1	
Product administered at inappropriate site	1	
Product dose omission in error	1	
Product dose omission issue	3	
Wrong product administered	1	
Product dispensing errors and issues		
Product dispensing error	1	
Site specific injuries NEC		
Limb injury	2	
Spinal column injury	1	
Skin injuries NEC		
Contusion	14	

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Underdoses NEC		
Prescribed underdose	1	0
Vaccination related complications		
Vaccination complication	13	0
Injuries SOC TOTAL	90	1

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Reaction Name	Total	Fatal
Investigations		
Autoimmunity analyses		
Anti-HLA antibody test positive	1	0
Blood gas and acid base analyses		
Oxygen saturation decreased	1	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose increased	2	0
Cardiac auscultatory investigations		
Cardiac murmur	2	0
Cardiac function diagnostic procedures		
Myocardial strain imaging	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF glucose decreased	1	0
CSF protein increased	1	0
Cholesterol analyses		
Blood cholesterol increased	1	0
Coagulation and bleeding analyses		
Fibrin D dimer increased	2	0
International normalised ratio increased	3	0
ECG investigations		
Electrocardiogram abnormal	1	0
Heart rate and pulse investigations		
Heart rate	7	0
Heart rate decreased	1	0
Heart rate increased	7	0
Heart rate irregular	1	0
Hepatobiliary imaging procedures		
Liver scan	1	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test	1	0
Quality of life decreased	1	0
Liver function analyses		
Liver function test	1	0
Mineral and electrolyte analyses		
Blood iron decreased	1	0
Blood potassium decreased	1	0
Physical examination procedures and organ system status		
Body temperature	2	0
Body temperature abnormal	1	0
Body temperature decreased	2	C
Body temperature fluctuation	1	0
Body temperature increased	4	C
Respiratory rate increased	1	C
Weight decreased	6	C
Weight increased	2	C
Platelet analyses		
Platelet count decreased	1	(
Platelet count increased	1	(
Red blood cell analyses		
Haemoglobin E	1	C
Haemoglobin decreased	1	C
Red cell distribution width increased	1	C

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Respiratory and pulmonary function diagnostic procedures		
Peak expiratory flow rate decreased	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Troponin increased	1	0
Therapeutic drug monitoring analyses		
Anticoagulation drug level below therapeutic	1	0
Triglyceride analyses		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	1	0
Blood pressure increased	8	0
Virus identification and serology		
SARS-CoV-2 test	1	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	2	0
White blood cell analyses		
Neutrophil count decreased	4	0
Neutrophil count increased	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	91	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	38	3 0
Hypophagia		2 0
Increased appetite		1 0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus		1 0
Diabetes mellitus inadequate control		1 0
Disorders of purine metabolism		
Gout	4	4 0
Electrolyte imbalance NEC		
Electrolyte imbalance		1 0
General nutritional disorders NEC		
Feeding disorder		1 0
Hyperglycaemic conditions NEC		
Hyperglycaemia		3 0
Phosphorus metabolism disorders		
Hypophosphataemia		1 0
Sodium imbalance		
Hyponatraemia		1 0
Total fluid volume decreased		
Dehydration	4	4 0
Water soluble vitamin deficiencies		
Folate deficiency		1 0
Metabolic disorders SOC TOTAL	59) 0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	9	(
Arthropathy Bone solution of a superstance	1	(
Bone related signs and symptoms		
Bone pain	5	(
Pain in jaw		(
Spinal pain	1	(
Bursal disorders		
Bursitis	1	(
Cartilage disorders		
Costochondritis	3	(
Connective tissue disorders NEC		
Polymyalgia rheumatica	4	(
Joint related disorders NEC		
Hypermobility syndrome	1	(
Joint lock	2	(
Periarthritis	2	(
Joint related signs and symptoms	07	
Arthralgia	97	(
Joint stiffness	3	(
Joint swelling	11	(
Lupus erythematosus (incl subtypes)		
Systemic lupus erythematosus	2	(
Muscle pains		
Fibromyalgia	2	(
Myalgia	85	(
Muscle related signs and symptoms NEC		
Muscle disorder	1	(
Muscle fatigue	3	(
Muscle spasms	17	(
Muscle tightness	2	(
Muscle twitching	3	(
Muscle tone abnormalities		
Muscle rigidity	4	(
Muscle weakness conditions	10	
Muscular weakness	18	(
Musculoskeletal and connective tissue conditions NEC		
Back disorder	1	(
Mobility decreased	12	(
Musculoskeletal disorder	1	(
Musculoskeletal stiffness	16	(
Musculoskeletal and connective tissue pain and discomfort		
Back pain	33	(
Limb discomfort	14	(
Musculoskeletal chest pain	2	(
Musculoskeletal discomfort	1	
Musculoskeletal pain	2	(
Neck pain	15	
Pain in extremity	121	
Psoriatic arthropathies		
Psoriatic arthropathy	1	
Rheumatoid arthropathies		
Rheumatoid arthritis	3	

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Soft tissue disorders NEC		
Axillary mass	1	0
Groin pain	2	0
Neck mass	2	0
Spondyloarthropathies		
Arthritis reactive	1	0
Tendon disorders		
Tendonitis	1	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	508	0

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Reaction Name	Total	Fatal
Neoplasms		
Breast and nipple neoplasms malignant		
Breast cancer	1	0
Breast cancer female	1	0
Haematologic neoplasms NEC		
Benign lymph node neoplasm	1	0
Leukaemias acute myeloid		
Acute myeloid leukaemia	1	1
Neoplasms malignant site unspecified NEC		
Malignant neoplasm progression	1	0
Neoplasm malignant	3	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Lung neoplasm malignant	1	1
Throat cancer	1	0
Skin neoplasms benign		
Skin papilloma	1	0
Neoplasms SOC TOTAL	11	2

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Reaction Name	<u> </u>	Fatal
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome	6	
Autonomic nervous system disorders		
Orthostatic intolerance	1	
Central nervous system haemorrhages and cerebrovascular accidents		
Basilar artery thrombosis	1	
Carotid artery occlusion	1	
Cerebrovascular accident	8	
Haemorrhage intracranial	2	
Ischaemic stroke	1	
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	1	
Coma states		
Coma	1	
Coordination and balance disturbances		
Balance disorder	10	
Coordination abnormal		
Dysstasia	2	
	2	
Cortical dysfunction NEC	3	
Aphasia	3	
Disturbances in consciousness NEC		
Lethargy	30	
Loss of consciousness	10	
Somnolence	15	
Syncope	18	
Dyskinesias and movement disorders NEC		
Bradykinesia	1	
Hypokinesia	1	
Movement disorder	2	
Encephalopathies NEC		
Autoimmune encephalopathy	1	
Eye movement disorders		
VIth nerve paralysis	1	
Facial cranial nerve disorders		
Bell's palsy	4	
Facial paralysis	7	
Facial paresis	1	
Facial spasm	1	
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	1	
Headaches NEC		
Cluster headache	1	
Headache	283	
Sinus headache	2	
Tension headache	6	
Increased intracranial pressure disorders		
Brain oedema	1	
Memory loss (excl dementia)		
Amnesia	7	
Memory impairment	3	
	3	
Meningitis NEC		
Meningitis noninfective Mental impairment (excl dementia and memory loss)	1	

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Reaction Name	Total	Fatal
ervous system disorders		
Cognitive disorder	1	
Disturbance in attention	3	
Mental impairment	1	
Migraine headaches		
Migraine	36	
Retinal migraine	1	
Mononeuropathies		
Carpal tunnel syndrome	1	
Peroneal nerve palsy	1	
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	
Muscle tone abnormal		
Hypotonia	1	
Narcolepsy and hypersomnia		
Hypersomnia	2	
Nervous system disorders NEC		
Nervous system disorder	2	
Neurological signs and symptoms NEC		
Dizziness	102	
Dizziness exertional	1	
Dizziness postural	7	
Head discomfort	2	
Meningism	1	
Myoclonus	1	
Neurological symptom	1	
Presyncope	3	
Unresponsive to stimuli	3	
Olfactory nerve disorders		
Anosmia	3	
Parosmia	4	
Paraesthesias and dysaesthesias		
Burning sensation	13	
Hypoaesthesia	35	
Paraesthesia	49	
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	
Hemiplegia	1	
Monoparesis	1	
Monoplegia	1	
Paralysis	3	
Parkinson's disease and parkinsonism		
Freezing phenomenon	2	
Parkinson's disease	1	
Peripheral neuropathies NEC		
Neuropathy peripheral	1	
Seizures and seizure disorders NEC		
Convulsions local	1	
Epilepsy	4	
Psychogenic seizure	1	
Seizure	10	
Seizure like phenomena	1	
Sensory abnormalities NEC		
Ageusia	6	

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Reaction Name Total Fatal Nervous system disorders WNervous system disorders cont'd 7 0 Dysgeusia Neuralgia 8 0 0 2 Restless legs syndrome 3 0 Sensory disturbance 0 Sensory loss 1 2 0 Taste disorder Speech and language abnormalities 5 0 Dysarthria Transient cerebrovascular events 4 0 Transient ischaemic attack Tremor (excl congenital) 0 Tremor 50 Trigeminal disorders Trigeminal neuralgia 0 1 Nervous system disorders SOC TOTAL 830 2

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Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	4	0
Maternal complications of pregnancy NEC		
Preterm premature rupture of membranes	1	0
Normal pregnancy, labour and delivery		
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Product supply and availability issues		
Product availability issue	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fata
sychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	
Anxiety symptoms		
Agitation	1	
Anxiety	9	
Nervousness	3	
Stress	3	
Behaviour and socialisation disturbances		
Personality change	1	
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	1	
Confusion and disorientation		
Confusional state	16	
Disorientation	5	
Deliria		
Delirium	1	
Depressive disorders		
Depression	4	
Dissociative states		
Dissociative amnesia	1	
Disturbances in initiating and maintaining sleep		
Insomnia	16	
Dyssomnias		
Poor quality sleep	2	
Emotional and mood disturbances NEC		
Anger	1	
Emotional disorder	1	
Irritability	1	
Mood altered	1	
Fluctuating mood symptoms		
Mood swings	2	
Hallucinations (excl sleep-related)		
Hallucination	5	
Increased physical activity levels		
Restlessness	3	
Mental disorders NEC		
Mental disorder	2	
Mood alterations with depressive symptoms		
Depressed mood	5	
Negative thoughts	1	
Mood disorders NEC		
Apathy	1	
Panic attacks and disorders		
Panic attack	4	
Parasomnias		
Abnormal dreams	1	
Nightmare	1	
Somnambulism	1	
Perception disturbances NEC		
Autoscopy	1	
Psychotic disorder NEC		
Acute psychosis	1	
Sleep disorders NEC		

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Reaction Name	Total	Fatal
Psychiatric disorders MPsychiatric disorders cont'd		
Sleep disorder	4	0
Stress disorders		
Post-traumatic stress disorder	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	1	0
Suicidal ideation	1	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	3	0
Psychiatric disorders SOC TOTAL	107	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	1	(
Pollakiuria	1	
Urinary incontinence	3	3
Urinary retention	2	2
Urine flow decreased	1	1
Bladder disorders NEC		
Bladder disorder	1	[] (
Urinary bladder haemorrhage	1	(
Glomerulonephritis and nephrotic syndrome		
Nephrotic syndrome	2	2 (
Nephritis NEC		
Nephritis	1	
Renal failure and impairment		
Acute kidney injury	2	2
Oliguria	1	
Renal failure	1	
Renal impairment	1	
Renal lithiasis		
Nephrolithiasis	2	2
Renal neoplasms		
Renal cyst	1	1
Renal vascular and ischaemic conditions		
Renal infarct	1	
Renal vein thrombosis	1	
Urinary abnormalities		
Chromaturia	1	
Haematuria	3	3
Urine odour abnormal		
Urinary tract signs and symptoms NEC		
Nocturia	1	
Renal pain		3
Renal & urinary disorders SOC TOTAL	32	

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Reaction Name	Total	Fatal
Reproductive & breast disorders Breast disorders NEC		
	2	
Breast mass	2	0
Breast signs and symptoms	4	
Breast pain	4	-
Breast swelling	1	0
Breast tenderness	1	0
Fallopian tube and ovary infections and inflammations		
Noninfective oophoritis	1	0
Menopausal effects NEC		
Menopausal symptoms	1	0
Premature menopause	3	0
Menopausal effects on the genitourinary tract		
Postmenopausal haemorrhage	2	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	20	
Intermenstrual bleeding	11	0
Menstrual disorder	18	
Menstruation irregular	23	0
Premenstrual syndrome	2	0
Menstruation with decreased bleeding		
Amenorrhoea	7	0
Hypomenorrhoea	4	0
Menstruation delayed	27	0
Oligomenorrhoea	1	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	41	0
Polymenorrhoea	7	0
Ovarian and fallopian tube disorders NEC		
Ovulation disorder	1	0
Ovulation pain	1	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	1	0
Pelvic haemorrhage	1	0
Prostatic signs, symptoms and disorders NEC	· ·	Ĭ
Prostatic pain	1	0
Reproductive tract signs and symptoms NEC	1	
Genital swelling	1	0
Pelvic pain	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	0	
	9	
Vulvovaginal disorder	1	C
Vulvovaginal signs and symptoms		
Vaginal discharge	1	
Reproductive & breast disorders SOC TOTAL	194	

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dysphoea	68	1
Dyspnoea exertional	1	
Hypopnoea	1	0
Respiratory arrest	1	
Tachypnoea	1	
Bronchospasm and obstruction		
Asthma	2	
Chronic obstructive pulmonary disease	2	1
Wheezing	4	
Conditions associated with abnormal gas exchange		
Hypoxia	1	0
Coughing and associated symptoms		
Cough	25	0
Haemoptysis	1	
Productive cough	6	
Laryngeal and adjacent sites disorders NEC (excl infections and		
neoplasms)		
Reflux laryngitis	1	0
Lower respiratory tract inflammatory and immunologic conditions		
Pneumonitis	1	
Lower respiratory tract signs and symptoms	-	
Pulmonary pain	2	0
Nasal congestion and inflammations	2	
Nasal congestion	3	0
Nasal disorders NEC	5	
Epistaxis	11	C
Paranasal sinus disorders (excl infections and neoplasms)		
Sinus congestion	1	0
Parenchymal lung disorders NEC		
Pulmonary fibrosis	1	
		0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal swelling	1	C
Pulmonary oedemas		
Pulmonary congestion	1	
Pulmonary thrombotic and embolic conditions	10	
Pulmonary embolism	13	3
Pulmonary thrombosis	1	1
Respiratory tract disorders NEC		
Lung disorder	1	
Pulmonary mass	1	
Upper respiratory tract signs and symptoms	_	
Dysphonia	1	
Nasal discomfort	1	
Oropharyngeal pain	17	0
Paranasal sinus discomfort	1	(
Rhinorrhoea	8	(
Sneezing	4	(
Throat irritation	3	
Yawning	2	
Respiratory disorders SOC TOTAL	188	

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Reaction Name kin disorders	Total	Fata
Acnes		
Acne	1	
Alopecias		
Alopecia	7	
Angioedemas		
Angioedema	4	
Apocrine and eccrine gland disorders		
Cold sweat	8	
Hyperhidrosis	45	
Night sweats	3	
Bullous conditions		
Blister	4	
Blister rupture	1	
Erythema multiforme	1	
Dermal and epidermal conditions NEC		
Dry skin	2	
Pain of skin	1	
Papule	2	
Scar pain	1	
Sensitive skin	3	
Skin burning sensation	2	
Skin discolouration	2	
Skin disorder	1	
Skin fissures	1	
Skin indentation	1	
Skin reaction	1	
Skin swelling	1	
Skin warm	1	
Yellow skin	1	
Dermatitis and eczema		
Dermatitis allergic	5	
Dermatitis atopic	1	
Eczema	4	
Seborrhoeic dermatitis	1	
	2	
Skin irritation	Z	
Erythemas	34	
Erythema <i>Exfoliative conditions</i>	34	
Skin exfoliation	2	
Hyperkeratoses		
Lichenoid keratosis	1	
Papulosquamous conditions		
Lichen planus	1	
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	
Pigmentation changes NEC		
Pigmentation disorder	1	
Pruritus NEC		
Pruritus	41	
Psoriatic conditions		
Guttate psoriasis	1	
Psoriasis	2	
Purpura and related conditions		1

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Petechiae	2	0
Rashes, eruptions and exanthems NEC		
Rash	68	0
Rash erythematous	8	0
Rash macular	3	0
Rash morbilliform	1	0
Rash papular	2	0
Rash pruritic	19	0
Rash vesicular	1	0
Scaly conditions		
Pityriasis	1	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
Urticarias		
Cold urticaria	2	0
Urticaria	18	0
Skin disorders SOC TOTAL	319	0

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Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Menopause	2	2 0
Postmenopause	1	0
Disability issues		
Bedridden	2	2 0
Housebound	1	0
Social circumstances SOC TOTAL	6	6 0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Contraceptive methods female		
Contraception	1	0
Immunisations		
COVID-19 immunisation	1	0
Immunisation	2	0
Joint therapeutic procedures		
Knee operation	1	0
Limb therapeutic procedures		
Foot operation	1	0
Nail therapeutic procedures		
Nail operation	1	0
Obstetric therapeutic procedures		
Caesarean section	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	1	0
Therapeutic procedures NEC		
Bed rest	1	0
Hospitalisation	1	0
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Vascular disorders		
Aneurysms and dissections non-site specific		-
Aneurysm	1	0
Aortic embolism and thrombosis	_	
Aortic embolus	2	0
Aortic thrombosis	1	0
Circulatory collapse and shock		
Circulatory collapse	2	0
Shock	3	0
Haemorrhages NEC		
Haematoma	1	0
Haemorrhage	22	0
Non-site specific embolism and thrombosis		
Thrombosis	11	0
Non-site specific vascular disorders NEC		
Vascular pain	2	0
Vascular rupture	1	0
Vein discolouration	1	0
Peripheral embolism and thrombosis		Ŭ
Deep vein thrombosis	12	0
Jugular vein thrombosis	1	0
Thrombophlebitis	1	0
Peripheral vascular disorders NEC	1	U
Erythromelalgia	1	0
Flushing	2	0
Hot flush	7	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	0
Peripheral coldness	2	0
Raynaud's phenomenon	1	0
Phlebitis NEC		0
Phlebitis	1	0
	1	0
Site specific vascular disorders NEC	1	0
Pallor	4	0
Varicose veins NEC		0
Spider vein		0
Varicose vein	1	0
Vascular hypertensive disorders NEC		-
Hypertension	15	0
Vascular hypotensive disorders		-
Hypotension	2	0
Vascular disorders SOC TOTAL	98	0
TOTAL REACTIONS FOR DRUG	4552	37
TOTAL REPORTS	1490	
	1490	07
TOTAL FATAL OUTCOME REPORTS		37