COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 31-Mar-2022

Data Lock Date: 30-Mar-2022 18:30:05

All UK spontaneous reports received up to and including 30/03/22 for COVID-19 vaccines where the brand has not been specified.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify 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	
Thrombocytopenia	9	0
Thrombosis with thrombocytopenia syndrome	1	0
White blood cell abnormal findings NEC		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	65	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	2	1
Cardiac signs and symptoms NEC		
Cardiac discomfort	2	0
Palpitations	43	0
Heart failures NEC		
Cardiac failure	1	0
Ischaemic coronary artery disorders		
Acute myocardial infarction	1	0
Angina pectoris	6	0
Myocardial infarction	8	2
Myocardial ischaemia	2	2
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	5	0
Pericardial disorders NEC		
Pericardial effusion	1	0
Rate and rhythm disorders NEC		
Bradycardia	1	0
Cardiac flutter	3	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	11	0
Supraventricular arrhythmias		
Atrial fibrillation	5	0
Atrial tachycardia	1	0
Supraventricular tachycardia	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	3	1
Cardiac disorders SOC TOTAL	105	6

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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
Adrenal gland disorders NEC		
Adrenal haemorrhage	2	0
Female gonadal function disorders		
Ovulation delayed	1	0
Thyroid hyperfunction disorders		
Thyrotoxic crisis	1	0
Endocrine disorders SOC TOTAL	5	0

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MedDRA Version: MedDRA 24.1	Total	Ectol
Reaction Name	lotai	Fatal
Eye disorders Charaid and vitro and attractive laborate days and do not provide a		
Choroid and vitreous structural change, deposit and degeneration	-	
Vitreous floaters	5	C
Corneal infections, oedemas and inflammations	4	
Keratitis	1	C
Eyelid movement disorders	4	
Blepharospasm	1	C
Iris and uveal tract infections, irritations and inflammations		
Iridocyclitis	1	C
Lacrimation disorders		
Dry eye	2	C
Lacrimation increased	2	C
Lid, lash and lacrimal infections, irritations and inflammations		
Chalazion	1	C
Eyelid cyst	1	C
Eyelid margin crusting	1	C
Swelling of eyelid	1	C
Ocular disorders NEC		
Eye disorder	4	
Eye pain	6	C
Eye swelling	8	
Ocular discomfort	1	C
Periorbital swelling	3	C
Ocular infections, inflammations and associated manifestations		
Eye allergy	1	C
Eye discharge	1	C
Eye pruritus	3	C
Ocular sensation disorders		
Photophobia Photophobia	4	C
Pupil disorders	4	
Pupil fixed	1	C
Pupils unequal	1	C
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal haemorrhage	1	C
Retinal vein occlusion	2	C
Retinal structural change, deposit and degeneration	4	
Macular degeneration	1	C
Retinal toxicity	1	C
Visual disorders NEC	_	
Diplopia	5	C
Photopsia	2	C
Vision blurred	14	(
Visual impairment and blindness (excl colour blindness)		_
Blindness	4	(
Blindness transient	1	(
Visual impairment	6	(
Eye disorders SOC TOTAL	86	

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Anal and rectal pains		
Proctalgia	1	0
Colitis (excl infective)		
Colitis	3	0
Colitis ulcerative	2	0
Crohn's disease	1	0
Dental pain and sensation disorders		
Toothache	3	0
Diarrhoea (excl infective)		
Diarrhoea	54	0
Dyspeptic signs and symptoms		
Dyspepsia	3	0
Faecal abnormalities NEC		
Abnormal faeces	2	0
Faeces discoloured	3	0
Flatulence, bloating and distension		
Abdominal distension	4	0
Flatulence	1	0
Gastritis (excl infective)		
Gastritis	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	12	0
Abdominal pain lower	3	0
Abdominal pain upper	27	0
Abdominal tenderness	1	0
Gastrointestinal pain	2	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	4	0
Gastrooesophageal reflux disease	3	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	16	0
Anal incontinence	1	0
Dysphagia	2	0
Gastrointestinal spastic and hypermotility disorders		_
Irritable bowel syndrome	2	0
Gastrointestinal stenosis and obstruction NEC	_	
lleus	1	0
Gastrointestinal vascular occlusion and infarction	·	Ŭ
Mesenteric vein thrombosis	1	0
Gingival disorders, signs and symptoms NEC	·	Ŭ
Gingival pain	2	0
	_	
• • • • • • • • • • • • • • • • • • • •	1	0
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		U
	1	1
Haematemesis	1	0
Haemorrhoids and gastrointestinal varices (excl oesophageal) Haemorrhoids Intestinal haemorrhages Intestinal haemorrhage Nausea and vomiting symptoms Nausea Retching Vomiting Vomiting projectile Non-site specific gastrointestinal haemorrhages Gastrointestinal haemorrhage	1 140 3 58 2	

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Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue disorders NEC		
Oral papule	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	2	0
Lip erythema	1	0
Lip exfoliation	1	0
Oral mucosal eruption	1	0
Oral pain	1	0
Paraesthesia oral	2	0
Oral soft tissue swelling and oedema		
Lip swelling	8	0
Mouth swelling	1	0
Stomatitis and ulceration		
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	390	1

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Reaction Name	Total_	<u>Fatal</u>
General disorders		
Administration site reactions NEC		
Administration site erythema	1	
Application and instillation site reactions		
Application site swelling	1	
Asthenic conditions		
Asthenia	46	
Chronic fatigue syndrome	1	
Fatigue	219	
Malaise	86	
Body temperature altered		
Hyperthermia	1	
Hypothermia	1	
Death and sudden death		
Death	13	1
Sudden death	1	
Febrile disorders		
Pyrexia	171	
Feelings and sensations NEC		
Chills	108	
Feeling abnormal	24	
Feeling cold	24	
Feeling hot	14	
Feeling of body temperature change	10	
Sensation of foreign body	1	
Thirst	5	
Gait disturbances		
Gait disturbance	8	
Gait inability	2	
General signs and symptoms NEC		
Condition aggravated	12	
Crying	2	
General physical health deterioration	3	
III-defined disorder	1	
Illness	31	
Influenza like illness	36	
Local reaction	1	
Peripheral swelling	40	
Secretion discharge	1	
Swelling	28	
Swelling face	14	
Symptom recurrence	1	
Unevaluable event	1	
Inflammations		
Inflammation	7	
Systemic inflammatory response syndrome	1	
Injection site reactions		
Injection site discomfort	1	
Injection site erythema	3	
Injection site inflammation	2	1
Injection site mass	6	1
Injection site pain	12	
Injection site pruritus	1	
Injection site reaction	1	

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site swelling	3	0
Injection site warmth	1	0
Interactions		
Drug interaction	2	0
Mass conditions NEC		
Cyst	2	0
Mass	1	0
Nodule	1	0
Oedema NEC		
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	11	0
Chest discomfort	8	0
Chest pain	38	0
Discomfort	7	0
Facial discomfort	1	0
Facial pain	4	0
Pain	94	. 0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse reaction	1	0
Drug ineffective	12	0
Drug intolerance	1	0
No reaction on previous exposure to drug	1	0
Surgical failure	1	0
Therapeutic product effect decreased	1	
Therapeutic product ineffective	1	0
Therapeutic response decreased	1	
Therapeutic response unexpected	1	0
Vaccination site reactions		
Shoulder injury related to vaccine administration	2	0
Vaccination site bruising	2 2	0
Vaccination site erythema	17	0
Vaccination site hypoaesthesia	1	
Vaccination site induration	2	· · · · · ·
Vaccination site inflammation	2 4	0
Vaccination site mass		
Vaccination site movement impairment	3	0
Vaccination site pain	17	0
Vaccination site papule	1	0
Vaccination site pruritus	3	0
Vaccination site rash	2	0
Vaccination site reaction	1	0
Vaccination site scab	1	0
Vaccination site swelling	15	C
Vaccination site warmth	6	
General disorders SOC TOTAL	1216	14

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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	7	0
Allergies to foods, food additives, drugs and other chemicals		
Allergy to vaccine	4	0
Drug hypersensitivity	3	0
Food allergy	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	2	0
Anaphylactic shock	1	0
Atopic disorders		
Seasonal allergy	1	0
Immune and associated conditions NEC		
Immune system disorder	1	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Transplant rejections		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	23	0

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Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Appendicitis	1	0
Bacterial infections NEC		
Arthritis bacterial	1	0
Cellulitis	3	0
Breast infections		
Mastitis	1	0
Caliciviral infections		
Norovirus infection	1	0
Candida infections		
Candida infection	1	0
Central nervous system and spinal infections		_
Encephalitis	1	0
Meningitis aseptic	1	0
Clostridia infections		
Clostridium difficile infection	1	0
Coronavirus infections	4.0	•
COVID-19	40	0
Post-acute COVID-19 syndrome	1	0
Suspected COVID-19	3	0
Eye and eyelid infections		0
Conjunctivitis	2	0
Eye infection	1	0
Hordeolum	1	0
Fungal infections NEC		0
Fungal infection	1	0
Herpes viral infections Disseminated varicella zoster vaccine virus infection	1	0
	2	0
Genital herpes	17	0
Herpes zoster Herpes zoster oticus	1	
Oral herpes	4	0
Varicella	1	0
Infections NEC	'	U
Abscess	1	0
Infection	9	0
Localised infection	1	0
Infectious transmissions	,	
Vaccine virus shedding	1	0
Influenza viral infections		J
Influenza	22	0
Lower respiratory tract and lung infections		_
Lower respiratory tract infection	3	1
Pneumonia	11	3
Mumps viral infections		
Mumps	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	2	0
Skin structures and soft tissue infections		
Rash pustular	1	0
Staphylococcal infections		
Furuncle	2	0
Trypanosomal infections		

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Reaction Name		Total	Fatal
Infections Infections	cont'd		
African trypanosomiasis		1	0
Upper respiratory tract infec	ctions		
Laryngitis		1	0
Nasopharyngitis		10	0
Sinusitis		1	0
Tonsillitis		2	0
Urinary tract infections			
Kidney infection		2	0
Urinary tract infection		4	0
Viral infections NEC			
Gastroenteritis viral		1	0
Sweating fever		1	0
Viral infection		3	0
Infections SOC TOTAL		166	4

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Reaction Name	<u> Total </u>	<u>Fatal</u>
<u>Injuries</u>		
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	2	(
Maternal exposure during breast feeding	1	(
Maternal exposure during pregnancy	9	(
Exposures to agents or circumstances NEC		
Exposure to vaccinated person	2	(
Eye injuries NEC		
Eye contusion	1	(
Eye injury	3	
Retinal injury	1	(
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	3	(
Incorrect route of product administration	1	(
Product administered at inappropriate site	4	
Product administration error	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	

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Reaction Name	Total	Fatal
Injuries cont'd		
Skin injuries NEC		
Contusion	15	0
Underdoses NEC		
Prescribed underdose	1	0
Vaccination related complications		
Vaccination complication	13	0
Injuries SOC TOTAL	100	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	i i	0
Chemistry analyses NEC		Ŭ
Inflammatory marker increased	1	0
Cholesterol analyses		J
Blood cholesterol increased	2	0
Coagulation and bleeding analyses		J
Fibrin D dimer increased	2	0
International normalised ratio increased	2	0
ECG investigations	٦	U
Electrocardiogram abnormal	1	0
Heart rate and pulse investigations	'	U
Heart rate	7	0
Heart rate decreased	1	0
Heart rate increased	8	0
Heart rate irregular	3	0
	٦	U
Hepatobiliary imaging procedures Liver scan	1	0
	'	0
Immunology skin tests NEC Skin test positive	1	0
	'	0
Investigations NEC Blood test	1	0
Blood test Blood test abnormal	1	0
	1	0
Quality of life decreased	'	U
Liver function analyses Liver function test	1	^
	1	0
Mineral and electrolyte analyses Blood iron decreased	1	0
	1	0
Blood potassium decreased	'	U
Physical examination procedures and organ system status	2	^
Body temperature	2	0
Body temperature abnormal		0
Body temperature decreased	4	0
Body temperature fluctuation	1	0
Body temperature increased	4	0
Respiratory rate increased	1 7	0
Weight decreased	/	0
Weight increased	2	0
Platelet analyses		_
Platelet count decreased	1	0
Platelet count increased	1	0
Red blood cell analyses		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
Red cell distribution width increased	1	0
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 abnormal	1	0
Blood pressure decreased	1	0
Blood pressure increased	9	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	3	0
Neutrophil count increased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	98	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	38	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	0
Electrolyte imbalance NEC		
Electrolyte imbalance	1	0
General nutritional disorders NEC		
Abnormal weight gain	1	0
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	0
Water soluble vitamin deficiencies		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	60	0

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Reaction Name MedDRA Version: MedDRA 24.1	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	13	0
Arthropathy	1	0
Palindromic rheumatism	1	0
Bone related signs and symptoms		
Bone pain	5	0
Pain in jaw	1	0
Spinal pain	1	0
Bursal disorders		
Bursitis	3	0
Cartilage disorders		
Costochondritis	3	0
Connective tissue disorders NEC		
Polymyalgia rheumatica	5	0
Joint related disorders NEC		
Hypermobility syndrome	1	0
Joint lock	2	0
Periarthritis	2	0
Rotator cuff syndrome	1	0
Joint related signs and symptoms		
Arthralgia	104	0
Joint stiffness	3	0
Joint swelling	11	0
Lupus erythematosus (incl subtypes)		
Systemic lupus erythematosus	2	0
Muscle pains		
Fibromyalgia	3	0
Myalgia	86	0
Muscle related signs and symptoms NEC		
Muscle disorder	1	0
Muscle fatigue	3	0
Muscle spasms	17	0
Muscle tightness	2 5	0
Muscle twitching	5	0
Muscle tone abnormalities		
Muscle rigidity	5	0
Muscle weakness conditions		
Muscular weakness	19	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	1	0
Mobility decreased	14	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	16	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	37	0
Limb discomfort	15	0
Musculoskeletal chest pain	2 1	0
Musculoskeletal discomfort		0
Musculoskeletal pain	2	0
Neck pain	15	0
Pain in extremity	132	0
Osteoarthropathies		
Osteoarthritis	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders le & tissue disorders cont'd		
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	4	0
Soft tissue disorders NEC		
Axillary mass	2	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	552	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
Lymphomas unspecified NEC		
Lymphoma	1	0
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
Respiratory tract small cell carcinomas		
Small cell lung cancer metastatic	1	1
Skin neoplasms benign		
Acrochordon	1	0
Skin papilloma	1	0
Uterine neoplasms benign		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	15	3

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MedDRA Version: MedDRA 24.1		
Reaction Name	<u> Total</u>	<u>Fatal</u>
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	(
Cerebral haemorrhage	1	(
Cerebral thrombosis	1	(
Cerebrovascular accident	10	•
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	2	(
Dysstasia	2	(
Cortical dysfunction NEC		
Aphasia	4	(
Dementia (excl Alzheimer's type)		
Dementia	1	(
Disturbances in consciousness NEC		
Lethargy	30	(
Loss of consciousness	13	(
Somnolence	15	(
Syncope	19	(
Dyskinesias and movement disorders NEC		
Bradykinesia	1	(
Hypokinesia	2	(
Movement disorder	2	(
Encephalopathies NEC		
Autoimmune encephalopathy	1	(
Eye movement disorders		
VIth nerve paralysis	1	(
Facial cranial nerve disorders		
Bell's palsy	3	(
Facial paralysis	6	(
Facial paresis	1	(
Facial spasm	1	(
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	1	(
Headaches NEC		
Cluster headache	1	(
Headache	291	
Sinus headache	2	(
Tension headache	6	
Increased intracranial pressure disorders		
Brain oedema	2	(
Lumbar spinal cord and nerve root disorders		
Sciatica	1	(

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Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Memory loss (excl dementia)		
Amnesia	8	(
Memory impairment	3	(
Meningitis NEC		
Meningitis noninfective	1	(
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	C
Disturbance in attention	3	C
Mental impairment	1	C
Migraine headaches		
Migraine	36	C
Retinal migraine	1	
Mononeuropathies		
Carpal tunnel syndrome	1	
Peroneal nerve palsy	1	C
Motor neurone diseases		
Motor neurone disease	1	C
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	C
Muscle tone abnormal		
Hypotonia	1	C
Narcolepsy and hypersomnia		
Hypersomnia	2	C
Nervous system disorders NEC		
Nervous system disorder	2	C
Neurological signs and symptoms NEC		
Dizziness	105	C
Dizziness exertional	1	
Dizziness postural	7	C
Head discomfort	2	
Meningism	1	C
Myoclonus	1	
Neurological symptom	2	C
Presyncope	3	
Unresponsive to stimuli	3	C
Olfactory nerve disorders		
Anosmia	3	C
Parosmia	4	
Paraesthesias and dysaesthesias		
Burning sensation	15	
Formication	1	C
Hypoaesthesia	35	
Paraesthesia	51	C
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	C
Hemiplegia	1	(
Monoparesis	1	(
Monoplegia	2	(
Paralysis	3	(
Parkinson's disease and parkinsonism		
Freezing phenomenon	2	(
Parkinson's disease	1	
Peripheral neuropathies NEC		

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Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Convulsions local	1	0
Epilepsy	5	0
Psychogenic seizure	1	0
Seizure	11	0
Seizure like phenomena	1	0
Sensory abnormalities NEC		
Ageusia	6	0
Dysgeusia	8	0
Neuralgia	8	0
Restless legs syndrome	2	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	2	0
Speech and language abnormalities		
Dysarthria	5	0
Transient cerebrovascular events		
Transient ischaemic attack	6	0
Tremor (excl congenital)		
Tremor	51	0
Trigeminal disorders		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	867	3

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Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	6	0
Maternal complications of pregnancy NEC		
Biochemical pregnancy	1	0
Preterm premature rupture of membranes	1	0
Normal pregnancy, labour and delivery		
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	9	0

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

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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	0
Anxiety symptoms		
Agitation	1	0
Anxiety	9	0
Nervousness	4	0
Stress	3	0
Behaviour and socialisation disturbances		
Personality change	1	0
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	2	0
Confusion and disorientation		
Confusional state	17	0
Disorientation	6	0
Deliria		
Delirium	1	0
Depressive disorders		
Depression	5	0
Dissociative states		_
Dissociative amnesia	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	15	
Middle insomnia	1	0
Dyssomnias		
Poor quality sleep	3	0
Emotional and mood disturbances NEC		
Anger	1	0
Emotional disorder	1	0
Irritability	1	0
Mood altered	1	0
Fluctuating mood symptoms	2	0
Mood swings	2	0
Hallucinations (excl sleep-related) Hallucination	5	0
	3	0
Increased physical activity levels Restlessness	3	0
Mental disorders NEC	3	U
Mental disorder Mental disorder	2	0
Mood alterations with depressive symptoms		U
Depressed mood	6	0
Negative thoughts	1	0
Mood disorders NEC	l l	
Apathy	1	0
Panic attacks and disorders		J
Panic attack	4	0
Parasomnias		
Abnormal dreams	1	0
Nightmare	1	Č
Somnambulism	1	Č
Perception disturbances NEC		
Autoscopy	1	C
Psychotic disorder NEC	l l	
Acute psychosis	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^P sychiatric disorders cont'd		
Sleep disorders NEC		
Sleep disorder	4	0
Stress disorders		
Post-traumatic stress disorder	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	1	0
Suicidal ideation	2	0
Suicide attempt	2	0
Thinking disturbances		
Bradyphrenia	3	0
Psychiatric disorders SOC TOTAL	116	0

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Reaction Name	Total	Fatal
Renal & urinary disorders	1000	
Bladder and urethral symptoms		
Dysuria	1 1	0
Pollakiuria	1	0
Urinary incontinence	3	
Urinary retention		
Urine flow decreased	2	l o
Bladder disorders NEC		
Bladder disorder	1 1	0
Urinary bladder haemorrhage	1	
Glomerulonephritis and nephrotic syndrome		
Nephrotic syndrome	2	0
Nephritis NEC		
Lupus nephritis	1	0
Nephritis	1	
Renal failure and impairment		
Acute kidney injury	2	0
Oliguria	1	0
Renal failure	1	0
Renal impairment	1	0
Renal lithiasis		
Nephrolithiasis	2	<u> </u>
Renal neoplasms		
Renal cyst		0
Renal vascular and ischaemic conditions		
Renal infarct	1	0
Renal vein thrombosis	1	0
Urinary abnormalities		
Chromaturia	1	0
Haematuria	3	8 0
Urine odour abnormal	1	0
Urinary tract signs and symptoms NEC		
Nocturia	1	0
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	33	<u> 0</u>

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Reproductive & breast disorders		
Breast disorders NEC		
Breast mass	2	(
Breast infections and inflammations		
Plasma cell mastitis	1	(
Breast signs and symptoms		
Breast pain	5	(
Breast swelling	1	(
Breast tenderness	1	(
Fallopian tube and ovary infections and inflammations		
Noninfective oophoritis	1	(
Menopausal effects NEC		
Menopausal symptoms	2	(
Premature menopause	3	(
Menopausal effects on the genitourinary tract		
Postmenopausal haemorrhage	2	(
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	22	
Intermenstrual bleeding	11	(
Menstrual disorder	19	
Menstruation irregular	27	(
Premenstrual syndrome	2	(
Menstruation with decreased bleeding		
Amenorrhoea	9	(
Hypomenorrhoea	4	(
Menstruation delayed	31	(
Oligomenorrhoea	1	(
Menstruation with increased bleeding		
Heavy menstrual bleeding	45	(
Polymenorrhoea	9	(
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst ruptured	1	(
Ovarian and fallopian tube disorders NEC		
Ovulation disorder	1	(
Ovulation pain	1	(
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	1	(
Pelvic haemorrhage	1	(
Prostatic signs, symptoms and disorders NEC		
Prostatic pain	1	(
Reproductive tract signs and symptoms NEC		
Genital swelling	1	(
Pelvic pain	2	(
Uterine disorders NEC		
Uterine pain	1	
Vulvovaginal disorders NEC		
Vaginal haemorrhage	10	
Vulvovaginal disorder	1	
Vulvovaginal signs and symptoms		
Vaginal discharge	1	
Reproductive & breast disorders SOC TOTAL	220	

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Reaction Name	Total	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	75	1
Dyspnoea exertional	1	0
Hypopnoea	1	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Tachypnoea	1	0
Bronchospasm and obstruction		
Asthma	4	0
Chronic obstructive pulmonary disease	2	1
Wheezing	5	0
Conditions associated with abnormal gas exchange		
Asphyxia	1	1
Нурохіа	1	0
Coughing and associated symptoms		
Cough	27	0
Haemoptysis	3	0
Productive cough	6	0
Laryngeal and adjacent sites disorders NEC (excl infections and		
neoplasms)		
Reflux laryngitis	1	0
Lower respiratory tract inflammatory and immunologic conditions		
Pneumonitis	1	0
Lower respiratory tract signs and symptoms		
Pulmonary pain	2	0
Nasal congestion and inflammations		
Nasal congestion	3	0
Nasal disorders NEC		
Epistaxis	12	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinus congestion	1	0
Parenchymal lung disorders NEC		
Emphysema	1	0
Pulmonary fibrosis	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal swelling	1	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	1	0
Pulmonary oedemas		
Pulmonary congestion	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	15	3
Pulmonary thrombosis	1	1
Respiratory tract disorders NEC		
Lung disorder	2	0
Pulmonary mass	1	0
Respiratory tract irritation	1	0
Upper respiratory tract signs and symptoms		
Aphonia	1	0
Dysphonia	1	C
Nasal discomfort	1	C
Oropharyngeal pain	16	0
Paranasal sinus discomfort	1	0

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Reaction Name	Total	Fatal
Respiratory disorders espiratory disorders cont'd		
Rhinorrhoea	8	0
Sneezing	4	0
Throat irritation	3	0
Throat tightness	1	0
Yawning	2	0
Respiratory disorders SOC TOTAL	212	7

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Skin disorders		
Acnes		
Acne	1	(
Alopecias		
Alopecia	7	(
Angioedemas		
Angioedema	4	(
Apocrine and eccrine gland disorders		
Cold sweat	9	(
Hyperhidrosis	45	
Night sweats	3	
Bullous conditions		
Blister	4	
Blister rupture	1	
Erythema multiforme	2	
Dermal and epidermal conditions NEC		
Dry skin	2	
Pain of skin	2 3	
Papule	3	
Scar pain	1	
Sensitive skin	2	
Skin burning sensation	2 2 5	
Skin discolouration	5	
Skin disorder	2	
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	6	
Eczema weeping	1	
Seborrhoeic dermatitis	1	
Skin irritation	2	
Erythemas		
Érythema	35	
Exfoliative conditions		
Skin exfoliation	2	
Hyperkeratoses		
Lichenoid keratosis	1	
Papulosquamous conditions		
Lichen planus	1	
Lichen sclerosus	1	
Parapsoriasis	1	
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	
Pigmentation changes NEC		
Pigmentation disorder	1	
Pilar disorders NEC		
Hair growth abnormal	1	
Pruritus NEC		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pruritus	46	0
Psoriatic conditions		
Guttate psoriasis	2	0
Psoriasis	3	0
Purpura and related conditions		
Petechiae	2	0
Purpura	1	0
Rashes, eruptions and exanthems NEC		
Rash	68	0
Rash erythematous	10	0
Rash macular	4	0
Rash morbilliform	1	0
Rash papular	2	0
Rash pruritic	20	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
Skin vasculitides		
Capillaritis	1	0
Skin vasomotor conditions		
Livedo reticularis	1	0
Urticarias		
Cold urticaria	2	0
Urticaria	19	0
Skin disorders SOC TOTAL	348	0

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Reaction Name	Total		Fatal
Social circumstances			
Age related issues			
Menopause		2	0
Postmenopause		1	0
Disability issues			
Bedridden		2	0
Housebound		1	0
Social issues NEC			
Impaired quality of life		1	0
Social circumstances SOC TOT	AL	7	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
Therapeutic procedures NEC		
Bed rest	1	0
Hospitalisation	1	0
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	11	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	3	0
Shock	3	0
Haemorrhages NEC		
Haematoma	1	0
Haemorrhage	22	0
Non-site specific embolism and thrombosis		
Thrombosis	12	0
Non-site specific vascular disorders NEC		
Vascular pain	2	0
Vascular rupture	1	0
Vein discolouration	1	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	12	0
Jugular vein thrombosis	1	0
Thrombophlebitis	1	0
Peripheral vascular disorders NEC		
Erythromelalgia	1	0
Flushing	2	0
Hot flush	7	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		_
Peripheral coldness	2	0
Peripheral ischaemia	2	0
Raynaud's phenomenon	1	Ö
Phlebitis NEC		J
Phlebitis	1	0
Site specific vascular disorders NEC	·	Ĭ
Pallor	5	0
Varicose veins NEC	J	
Spider vein	1	0
Varicose vein	1	Ö
Vascular hypertensive disorders NEC	'	١
Hypertension	20	0
Vascular hypotensive disorders	20	١
Hypotension	2	0
Vasculitides NEC		٠
Vasculitis	1	_
	107	0
Vascular disorders SOC TOTAL TOTAL REACTIONS FOR DRUG	107	43
IOTAL REACTIONS FOR DRUG	4887	43
TOTAL DEPORTS	4000	
TOTAL REPORTS	1608	
TOTAL FATAL OUTCOME REPORTS		43