## COVID-19 brand unspecified Vaccine Analysis Print

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All UK spontaneous reports received up to and including 10/11/2021 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.

Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Iron deficiency anaemia	•	1 0
Anaemias NEC		
Anaemia	3	3 0
Anaemias haemolytic NEC		
Haemolytic anaemia	•	1 0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	•	1 0
Eosinophilic disorders		
Eosinophilia	•	1 0
Haematological disorders		
Blood disorder	•	1 1
Lymphatic system disorders NEC		
Lymph node pain	3	3 0
Lymphadenitis	•	1 0
Lymphadenopathy	23	3 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	4	4 3
Thrombocytopenia	3	3 0
Blood disorders SOC TOTAL	5 <sup>2</sup>	ıl 4

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac conduction disorders		
Bundle branch block	1	0
Cardiac disorders NEC		
Cardiac disorder	1	0
Cardiac signs and symptoms NEC		
Cardiac discomfort	2	0
Palpitations	17	0
Ischaemic coronary artery disorders		
Acute myocardial infarction	1	0
Angina pectoris	3	0
Myocardial infarction	9	3
Myocardial disorders NEC		
Left ventricular dysfunction	1	0
Noninfectious myocarditis		
Immune-mediated myocarditis	1	0
Myocarditis	1	0
Noninfectious pericarditis		
Pericarditis	1	0
Rate and rhythm disorders NEC		
Bradycardia	1	0
Cardiac flutter	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	4	0
Supraventricular arrhythmias		
Atrial fibrillation	4	0
Supraventricular tachycardia	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	1	1
Cardiac disorders SOC TOTAL	51	4

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

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	2	0
Ear disorder	1	0
Ear pain	5	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	2	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	16	0
Vertigo	10	0
Ear disorders SOC TOTAL	48	0

Reaction Name	Total	Fatal
Endocrine disorders		
Female gonadal function disorders		
Ovulation delayed	1	0
Endocrine disorders SOC TOTAL	1	l o

Reaction Name	Total	Fatal
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	5	0
Corneal infections, oedemas and inflammations		
Keratitis	1	0
Iris and uveal tract infections, irritations and inflammations		
Iridocyclitis	1	0
Lacrimation disorders		
Dry eye	2	0
Lacrimation increased	2	0
Lid, lash and lacrimal infections, irritations and inflammations		
Chalazion	1	0
Eyelid cyst	1	0
Swelling of eyelid	1	0
Ocular disorders NEC		
Eye disorder	2	0
Eye pain	5	0
Eye swelling	8	0
Ocular discomfort	1	0
Periorbital swelling	3	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	1	0
Eye pruritus	3	0
Ocular sensation disorders		
Photophobia	4	0
Pupil disorders		
Pupil fixed	1	0
Pupils unequal	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	1	0
Retinal toxicity	1	0
Visual disorders NEC		
Diplopia	4	0
Photopsia	2	0
Vision blurred	10	0
Visual impairment and blindness (excl colour blindness)		
Blindness	4	0
Blindness transient	1	0
Visual impairment	3	0
Eve disorders SOC TOTAL	72	Ö

Reaction Name	Total	Fatal
Sastrointestinal 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	40	
Dyspeptic signs and symptoms		
Dyspepsia	3	
Faecal abnormalities NEC		
Abnormal faeces	2	
Faeces discoloured	3	
Flatulence, bloating and distension		
Abdominal distension	4	
Gastritis (excl infective)		
Gastritis	1	
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	10	
Abdominal pain lower	2	
Abdominal pain upper	24	
Abdominal tenderness	1	
Gastrointestinal pain	2	
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	3	
Gastrooesophageal reflux disease	3	
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	15	
Dysphagia	2	l .
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	112	
Retching	2	
Vomiting	43	
Vomiting projectile	2	
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	1	
Haematemesis	1	
Oral dryness and saliva altered		
Dry mouth	1	

Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
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	6	0
Stomatitis and ulceration		
Mouth ulceration	3	0
Tongue disorders		
Glossitis	1	0
Tongue signs and symptoms		
Glossodynia	1	0
Swollen tongue	2	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	312	1

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	34	
Chronic fatigue syndrome	1	0
Fatigue	170	ı
Malaise	73	( C
Body temperature altered		
Hyperthermia	1	
Death and sudden death		
Death	11	11
Sudden death	1	1
Febrile disorders		
Pyrexia	139	(
Feelings and sensations NEC		
Chills	95	c
Feeling abnormal	20	
Feeling cold	22	0
Feeling hot	13	(
Feeling of body temperature change	7	(
Sensation of foreign body	1	
Thirst	4	l c
Gait disturbances		
Gait disturbance	5	l c
Gait inability	2	
General signs and symptoms NEC		
Condition aggravated	7	
Crying	2	
General physical health deterioration	3	
Illness	25	
Influenza like illness	30	ı
Local reaction	1	l c
Peripheral swelling	28	
Secretion discharge	1	
Swelling	20	
Swelling face	11	
Symptom recurrence	1	
Unevaluable event	1	
Inflammations		
Inflammation	5	1 0
Systemic inflammatory response syndrome	1	
Injection site reactions		
Injection site discomfort	1	(
Injection site erythema	3	
Injection site inflammation		
Injection site mass	5	
Injection site mass Injection site pain	8	
Injection site pain	0	
Injection site swelling	1	
Mass conditions NEC		
Cyst	1	C

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Nodule	1	0
Oedema NEC		
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	4	0
Chest discomfort	7	0
Chest pain	21	0
Discomfort	6	0
Facial discomfort	1	0
Facial pain	3	0
Pain	71	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	3	0
Drug ineffective	2	0
Drug intolerance	1	0
No reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	1	0
Therapeutic product ineffective	1	0
Therapeutic response decreased	1	0
Therapeutic response unexpected	1	0
Vaccination site reactions		
Vaccination site bruising	1	0
Vaccination site erythema	14	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	1	0
Vaccination site inflammation	2	0
Vaccination site mass	4	0
Vaccination site movement impairment	1	0
Vaccination site pain	11	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	8	0
Vaccination site warmth	4	0
General disorders SOC TOTAL	940	12

Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	1	0
Hepatic vascular disorders		
Portal vein thrombosis	3	0
Hepatic disorders SOC TOTAL	4	l o

Reaction Name	Total	Fatal
Immune system disorders		
Acute and chronic sarcoidosis		
Sarcoidosis	1	0
Allergic conditions NEC		
Hypersensitivity	4	0
Allergies to foods, food additives, drugs and other chemicals		
Allergy to vaccine	3	0
Drug hypersensitivity	2	0
Food allergy	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	3	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	18	0

Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Appendicitis	1	0
Bacterial infections NEC		
Arthritis bacterial	1	0
Breast infections		
Mastitis	1	0
Caliciviral infections		
Norovirus infection	1	0
Central nervous system and spinal infections		
Encephalitis	1	0
Meningitis aseptic	1	0
Coronavirus infections		
COVID-19	18	0
Suspected COVID-19	1	0
Eye and eyelid infections		
Eye infection	1	0
Hordeolum	1	0
Fungal infections NEC		
Fungal infection	1	0
Herpes viral infections		
Genital herpes	2	0
Herpes zoster	11	0
Oral herpes	3	0
Infections NEC		
Infection	6	0
Localised infection	1	0
Infectious transmissions		
Vaccine virus shedding	1	0
Influenza viral infections		
Influenza	17	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	3	1
Pneumonia	8	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	1	0
Trypanosomal infections		
African trypanosomiasis	1	0
Upper respiratory tract infections		
Laryngitis	1	0
Nasopharyngitis	8	0
Sinusitis	1	0
Tonsillitis	2	0
Urinary tract infections		
Kidney infection	2	0
Urinary tract infection	3	0
Viral infections NEC		
Gastroenteritis viral	1	0

<b>Reaction Name</b>		Total	Fatal
Infections	Infections cont'd		
Post viral fatigu	e syndrome	1	0
Sweating fever		1	0
Viral infection		2	0
Infections SOC TO	TAL	108	4

Reaction Name	<u> Total</u>	<u>Fatal</u>
njuries		
Bone and joint injuries NEC		
Joint injury	1	(
Cerebral injuries NEC		
Subdural haematoma	1	
Exposures associated with pregnancy, delivery and lactation		
Maternal exposure during breast feeding	1	(
Maternal exposure during pregnancy	4	(
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	1	
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	
Non-site specific injuries NEC		
Fall	9	
Non-site specific procedural complications		
Incision site pain	1	
Injection related reaction	2	
Overdoses NEC		
Overdose Overdose	1	
Product administration errors and issues	· ·	
Incorrect route of product administration	1	
Product administered at inappropriate site	1	
Product dose omission in error	1	
Product dose omission issue	2	
Wrong product administered	1	
Product dispensing errors and issues  Product dispensing error	1	
Site specific injuries NEC	1	
Limb injury		
Spinal column injury		
Skin injuries NEC	40	
Contusion	13	
Underdoses NEC		
Prescribed underdose	1	
Vaccination related complications		
Vaccination complication	10	
iuries SOC TOTAL	70	1

Reaction Name	Total	Fatal
Investigations		
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
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
Heart rate and pulse investigations		
Heart rate	7	0
Heart rate decreased	1	0
Heart rate increased	5	0
Heart rate irregular	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	0
Body temperature fluctuation	1	0
Body temperature increased	2	0
Weight decreased	5	0
Weight increased	1	0
Platelet analyses		
Platelet count decreased	1	0
Red blood cell analyses		
Haemoglobin E	1	0
Haemoglobin decreased	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
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

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	3	0
Investigations SOC TOTAL	73	0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	34	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
Hyperglycaemic conditions NEC		
Hyperglycaemia	2	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Sodium imbalance		
Hyponatraemia	1	0
Total fluid volume decreased		
Dehydration	3	0
Water soluble vitamin deficiencies		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	52	0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	5	0
Arthropathy	1	0
Bone related signs and symptoms		
Bone pain	4	0
Spinal pain	1	0
Bursal disorders		
Bursitis	1	0
Cartilage disorders		
Costochondritis	3	C
Connective tissue disorders NEC		
Polymyalgia rheumatica	3	C
Joint related disorders NEC		
Hypermobility syndrome	1	C
Joint lock	1	C
Periarthritis	2	(
Joint related signs and symptoms		
Arthralgia	77	C
Joint stiffness	2	C
Joint swelling	10	C
Lupus erythematosus (incl subtypes)		
Systemic lupus erythematosus	1	C
Muscle pains		
Fibromyalgia	3	C
Myalgia	70	C
Muscle related signs and symptoms NEC		
Muscle fatigue	3	C
Muscle spasms	12	C
Muscle tightness	2	(
Muscle twitching	1	(
Muscle tone abnormalities		
Muscle rigidity	4	C
Muscle weakness conditions		
Muscular weakness	12	C
Musculoskeletal and connective tissue conditions NEC		
Back disorder	1	(
Mobility decreased	12	Č
Musculoskeletal stiffness	12	Ċ
Musculoskeletal and connective tissue pain and discomfort		
Back pain	25	C
Limb discomfort	10	Č
Musculoskeletal chest pain	1	Ċ
Musculoskeletal discomfort	i i	Č
Musculoskeletal pain	2	Ċ
Neck pain	14	Č
Pain in extremity	102	Ċ
Psoriatic arthropathies		
Psoriatic arthropathy	1	(
Rheumatoid arthropathies		
Rheumatoid arthritis	2	(
Soft tissue disorders NEC		
Groin pain	1	(
Spondyloarthropathies		

Reaction Name	Total	Fatal
Muscle & tissue disorders  Muscle & tissue disorders cont'd		
Arthritis reactive	1	0
Tendon disorders		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	405	o l

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 chronic lymphocytic		
Chronic lymphocytic leukaemia	1	0
Neoplasms malignant site unspecified NEC		
Malignant neoplasm progression	1	0
Neoplasm malignant	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Throat cancer	1	0
Skin neoplasms benign		
Skin papilloma	1	0
Neoplasms SOC TOTAL	8	0

Reaction Name	<u>Total</u>	Fatal
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome	5	0
Autonomic nervous system disorders		
Orthostatic intolerance	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Basilar artery thrombosis	1	1
Carotid artery occlusion	1	0
Cerebrovascular accident	7	0
Haemorrhage intracranial	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	1	1
Coma states		
Coma	1	0
Coordination and balance disturbances		
Balance disorder	9	0
Coordination abnormal	2	0
Dysstasia	2	0
Cortical dysfunction NEC		
Aphasia	2	0
Disturbances in consciousness NEC		
Lethargy	26	0
Loss of consciousness	7	0
Somnolence	14	0
Syncope	15	0
Dyskinesias and movement disorders NEC		
Bradykinesia	1	0
Hypokinesia	1	0
Encephalopathies NEC		,
Autoimmune encephalopathy	1	0
Eye movement disorders		,
VIth nerve paralysis	1	0
Facial cranial nerve disorders		,
Bell's palsy	2	0
Facial paralysis	5	0
Facial paresis	1	0
Headaches NEC		Ŭ
Cluster headache	1	0
Headache	244	0
Sinus headache	2	0
Tension headache	5	0
Increased intracranial pressure disorders	Ĭ	J
Brain oedema	1	0
Memory loss (excl dementia)		J
Amnesia	6	0
Memory impairment	2	0
Meningitis NEC	_	
Meningitis noninfective	1	0
Mental impairment (excl dementia and memory loss)	'	
Cognitive disorder	1	0
Disturbance in attention	3	0
Mental impairment	1	0
Migraine headaches		U
Migraine neadaches Migraine	31	0

Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Retinal migraine	1	0
Mononeuropathies		_
Carpal tunnel syndrome	1	0
Multiple sclerosis acute and progressive		0
Multiple sclerosis	2	0
Narcolepsy and hypersomnia		_
Hypersomnia	1	0
Nervous system disorders NEC		_
Nervous system disorder	2	0
Neurological signs and symptoms NEC		_
Dizziness	87	0
Dizziness postural	7	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	2	0
Unresponsive to stimuli	2	0
Olfactory nerve disorders		
Anosmia	1	0
Parosmia	2	0
Paraesthesias and dysaesthesias		
Burning sensation	7	0
Hypoaesthesia	26	0
Paraesthesia	34	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	0
Hemiplegia	1	0
Monoplegia	1	0
Paralysis	2	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	1	0
Parkinson's disease	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Convulsions local	1	0
Epilepsy	2	0
Seizure	8	0
Seizure like phenomena	1	0
Sensory abnormalities NEC		
Ageusia	4	0
Dysgeusia	6	0
Neuralgia	7	0
Restless legs syndrome	2	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	1	0
Speech and language abnormalities		
Dysarthria	5	0
Transient cerebrovascular events		
Transient ischaemic attack	3	0
Tremor (excl congenital)		U
Tremor	43	0

Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Trigeminal disorders		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	680	2

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	3	3 0
Maternal complications of pregnancy NEC		
Preterm premature rupture of membranes	1	ı  o
Normal pregnancy, labour and delivery		
Pregnancy	1	ı  o
Pregnancy conditions SOC TOTAL		5 0

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

Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	0
Anxiety symptoms		
Anxiety	8	
Nervousness	2 2	0
Stress	2	0
Behaviour and socialisation disturbances		
Personality change	1	0
Confusion and disorientation		
Confusional state	15	
Disorientation	5	0
Deliria		
Delirium	1	0
Depressive disorders		
Depression	2	0
Dissociative states		
Dissociative amnesia	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	12	0
Dyssomnias		
Poor quality sleep	2	0
Emotional and mood disturbances NEC		
Anger	1	0
Emotional disorder	1	0
Irritability	1	0
Mood altered	1	0
Fluctuating mood symptoms		
Mood swings	2	0
Hallucinations (excl sleep-related)		
Hallucination	5	0
Increased physical activity levels		
Restlessness	2	0
Mental disorders NEC		
Mental disorder	2	0
Mood alterations with depressive symptoms		
Depressed mood	4	0
Negative thoughts	1	0
Panic attacks and disorders		
Panic attack	2	0
Parasomnias		
Nightmare	1	0
Perception disturbances NEC		
Autoscopy	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Sleep disorders NEC		
Sleep disorder	4	0
Suicidal and self-injurious behaviour		
Intentional self-injury	1	C
Suicidal ideation	1	
Suicide attempt	i i	Ö
Thinking disturbances		
Bradyphrenia	3	C

Reaction Name		Total	Fatal
Psychiatric disorders	Psychiatric disorders cont'd		
Psychiatric disorders	SOC TOTAL	87	0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	•	1 0
Urinary incontinence	3	3 0
Urine flow decreased	•	1 0
Bladder disorders NEC		
Bladder disorder	•	1 0
Glomerulonephritis and nephrotic syndrome		
Nephrotic syndrome	2	2 0
Nephritis NEC		
Nephritis	•	1 0
Renal failure and impairment		
Acute kidney injury		2 0
Renal impairment	•	1 0
Renal lithiasis		
Nephrolithiasis	2	2 0
Renal neoplasms		
Renal cyst	•	1 0
Renal vascular and ischaemic conditions		
Renal infarct	•	1 0
Renal vein thrombosis	•	1 0
Urinary abnormalities		
Chromaturia	•	1 0
Haematuria	2	2 0
Urine odour abnormal	•	1 0
Urinary tract signs and symptoms NEC		
Nocturia	•	1 0
Renal pain	3	3 0
Renal & urinary disorders SOC TOTAL	25	5 0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast signs and symptoms		
Breast pain	2	0
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	1	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	14	0
Intermenstrual bleeding	10	0
Menstrual disorder	16	0
Menstruation irregular	15	0
Premenstrual syndrome	2	0
Menstruation with decreased bleeding		
Amenorrhoea	5	0
Hypomenorrhoea	4	0
Menstruation delayed	22	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	34	0
Polymenorrhoea	5	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		
Prostatic pain	1	0
Reproductive tract signs and symptoms NEC		
Genital swelling	1	0
Pelvic pain	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	8	0
Vulvovaginal signs and symptoms		
Vaginal discharge	1	0
Reproductive & breast disorders SOC TOTAL	153	0

Reaction Name         Total           Respiratory disorders             Breathing abnormalities             Dyspnoea         49           Hypopnoea         1           Respiratory arrest         1           Tachypnoea         1           Bronchospasm and obstruction	1 0 0 0 0
Dyspnoea49Hypopnoea1Respiratory arrest1Tachypnoea1	0 0
Hypopnoea 1 Respiratory arrest 1 Tachypnoea 1	0 0
Hypopnoea 1 Respiratory arrest 1 Tachypnoea 1	0 0
Respiratory arrest 1 Tachypnoea 1	0
Tachypnoea 1	0
	0
อาบาเดาบรมสราก สาเน บมรถนดเบา	0
Asthma 2	0
Chronic obstructive pulmonary disease	0
Wheezing 2	1
Coughing and associated symptoms	
Cough 17	0
Haemoptysis 1	0
Productive cough 3	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
Nasal congestion and inflammations	
Nasal congestion 3	0
Nasal disorders NEC	
Epistaxis 10	0
Paranasal sinus disorders (excl infections and neoplasms)	
Sinus congestion 1	0
Parenchymal lung disorders NEC	Ŭ
Pulmonary fibrosis 1	0
Pharyngeal disorders (excl infections and neoplasms)	
Pharyngeal swelling 1	0
Pulmonary oedemas	Ŭ
Pulmonary congestion 1	0
Pulmonary thrombotic and embolic conditions	Ŭ
Pulmonary embolism 11	2
Pulmonary thrombosis 1	1
Respiratory tract disorders NEC	•
Lung disorder 1	0
Pulmonary mass 1	0
Upper respiratory tract signs and symptoms	Ŭ
Nasal discomfort	0
Oropharyngeal pain 13	0
Paranasal sinus discomfort	0
Rhinorrhoea 5	0
	0
Sneezing 2 Throat irritation 2	0
	0
Yawning 2 Respiratory disorders SOC TOTAL 137	0

Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	1	0
Alopecias		
Alopecia	6	0
Angioedemas		
Angioedema	4	0
Apocrine and eccrine gland disorders		
Cold sweat	7	0
Hyperhidrosis	37	0
Night sweats	3	0
Bullous conditions		
Blister	3	0
Erythema multiforme	1	0
Dermal and epidermal conditions NEC		
Dry skin	2	0
Pain of skin	1	0
Papule	1	0
Scar pain	1	0
Sensitive skin	2 2	0
Skin burning sensation		0
Skin discolouration	2	0
Skin disorder	1	0
Skin fissures	1	0
Skin indentation	1	0
Skin reaction	1	0
Skin swelling	1	0
Skin warm	1	0
Yellow skin	1	0
Dermatitis and eczema		
Dermatitis allergic	4	0
Eczema	3	0
Seborrhoeic dermatitis	1	0
Skin irritation	2	0
Erythemas		
Erythema	26	0
Exfoliative conditions		
Skin exfoliation	2	0
Hyperkeratoses		
Lichenoid keratosis	1	0
Papulosquamous conditions		
Lichen planus	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Pigmentation changes NEC		
Pigmentation disorder	1	0
Pruritus NEC		
Pruritus	33	0
Purpura and related conditions		
Petechiae	2	0
Rashes, eruptions and exanthems NEC		
Rash	62	0
Rash erythematous	7	0
Rash macular	3	

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash morbilliform	1	0
Rash papular	1	0
Rash pruritic	15	5 0
Rash vesicular	1	0
Scaly conditions		
Pityriasis	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
Urticarias		
Cold urticaria	2	0
Urticaria	16	0
Skin disorders SOC TOTAL	268	sl ol

Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Menopause	2	<u>2</u> 0
Postmenopause	1	0 0
Disability issues		
Bedridden	1	ı  o
Social circumstances SOC TOTAL	4	ıl o

Reaction Name	Total	Fatal
Surgical & medical procedures		
Contraceptive methods female		
Contraception	,	1 0
Immunisations		
COVID-19 immunisation	•	I 0
Immunisation	•	0
Joint therapeutic procedures		
Knee operation	•	0
Nail therapeutic procedures		
Nail operation	•	1 0
Therapeutic procedures NEC		
Bed rest	•	0
Hospitalisation		0
Surgical & medical procedures SOC TOTAL		<i>r</i> l 0

Reaction Name	Total	Fatal
/ascular disorders		
Aneurysms and dissections non-site specific		
Aneurysm	1	(
Aortic embolism and thrombosis		
Aortic embolus	2	[ C
Aortic thrombosis	_   1	
Circulatory collapse and shock		
Circulatory collapse	3	(
Shock	3	0
Haemorrhages NEC		
Haematoma	1	(
Haemorrhage	18	
Non-site specific embolism and thrombosis		
Thrombosis	9	(
Non-site specific vascular disorders NEC		
Vascular pain	2	
Vascular rupture	1	(
Vein discolouration	1	
Peripheral embolism and thrombosis		
Deep vein thrombosis	10	
Jugular vein thrombosis	1	l c
Thrombophlebitis	1	1 0
Peripheral vascular disorders NEC		
Erythromelalgia	1	C
Flushing	2	
Hot flush	6	
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	2	C
Raynaud's phenomenon	1 1	
Phlebitis NEC		
Phlebitis	1	l c
Site specific vascular disorders NEC		
Pallor	3	l c
Varicose veins NEC		
Spider vein	1	(
Varicose vein	1	ı
Vascular hypertensive disorders NEC	·	
Hypertension	11	
Vascular hypotensive disorders	' '	
Hypotension	2	
/ascular disorders SOC TOTAL	84	
TOTAL REACTIONS FOR DRUG	3665	
	3005	34
TOTAL DEPONTS	4004	
TOTAL REPORTS	1224	
OTAL FATAL OUTCOME REPORTS		з