

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Jan-2021
Data Lock Date: 27-Jan-2021 19:00:04

ALL UK spontaneous reports received between 4/01/21 and 24/01/21 for COVID-19 vaccine AstraZeneca/Oxford

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Reaction Name	Total	Fatal
Blood disorders		
<i>Leukopenias NEC</i>		
Leukopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	8	0
Lymphadenitis	1	0
Lymphadenopathy	92	0
<i>Neutropenias</i>		
Neutropenia	5	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	108	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	106	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	3	0
Cardiac flutter	3	0
Extrasystoles	1	0
Tachyarrhythmia	1	0
Tachycardia	86	0
<i>Supraventricular arrhythmias</i>		
Sinus tachycardia	5	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac disorders SOC TOTAL	212	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	42	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	3	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	14	0
Vertigo	12	0
Vertigo positional	1	0
Ear disorders SOC TOTAL	76	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
Endocrine disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Eyelid movement disorders</i>		
Eyelid ptosis	1	0
<i>Lacrimation disorders</i>		
Dry eye	5	0
Lacrimation increased	5	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye pain	115	0
Eye swelling	12	0
Periorbital swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye irritation	6	0
Eye pruritus	8	0
Ocular hyperaemia	4	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	2	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	4	0
Foreign body sensation in eyes	1	0
Photophobia	32	0
<i>Pupil disorders</i>		
Miosis	1	0
Pupils unequal	1	0
<i>Visual disorders NEC</i>		
Diplopia	2	0
Photopsia	3	0
Vision blurred	28	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	3	0
Blindness transient	2	0
Visual acuity reduced	1	0
Visual impairment	4	0
Eye disorders SOC TOTAL	246	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	217	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	11	0
Epigastric discomfort	1	0
Eructation	2	0
<i>Faecal abnormalities NEC</i>		
Faeces soft	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	11	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	106	0
Abdominal pain lower	2	0
Abdominal pain upper	104	0
Abdominal rigidity	1	0
Abdominal tenderness	1	0
Gastrointestinal pain	9	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	4	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	25	0
Dysphagia	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Irritable bowel syndrome	2	0
Oesophageal spasm	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	2	0
Gingival pain	4	0
Gingival pruritus	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	1171	0
Retching	3	0
Vomiting	407	0
Vomiting projectile	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	34	0
Salivary hypersecretion	3	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
Lip disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	13	0
Lip pain	2	0
Lip pruritus	1	0
Oral discomfort	1	0
Oral pain	7	0
Paraesthesia oral	28	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	22	0
Mouth swelling	5	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	2	0
Mouth ulceration	7	0
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	2	0
Swollen tongue	15	0
Tongue blistering	1	0
Gastrointestinal disorders SOC TOTAL	2258	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Puncture site pain	1	0
Puncture site reaction	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	125	0
Fatigue	1281	0
Malaise	239	1
<i>Body temperature altered</i>		
Hypothermia	3	0
<i>Death and sudden death</i>		
Death	26	20
Sudden death	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	5	0
Pyrexia	2446	0
<i>Feelings and sensations NEC</i>		
Chills	1451	0
Feeling abnormal	56	0
Feeling cold	141	0
Feeling hot	42	0
Feeling jittery	1	0
Feeling of body temperature change	48	0
Hunger	2	0
Sensation of foreign body	2	0
Temperature intolerance	2	0
Thirst	46	0
<i>Fibrosis NEC</i>		
Fibrosis	1	0
<i>Gait disturbances</i>		
Gait disturbance	5	0
Gait inability	4	0
Loss of control of legs	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crying	1	0
Energy increased	1	0
General physical health deterioration	4	0
Illness	166	0
Influenza like illness	262	0
Local reaction	14	0
Peripheral swelling	113	0
Swelling	57	0
Swelling face	18	0
<i>Inflammations</i>		
Inflammation	5	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	2	0
Injection site erythema	18	0
Injection site hypoaesthesia	1	0
Injection site induration	1	0
Injection site inflammation	4	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site joint pain	2	0
Injection site mass	35	0
Injection site oedema	3	0
Injection site pain	148	0
Injection site paraesthesia	1	0
Injection site pruritus	9	0
Injection site rash	7	0
Injection site reaction	5	0
Injection site swelling	11	0
Injection site warmth	14	0
Interactions		
Drug interaction	1	0
Mass conditions NEC		
Mass	1	0
Mucosal findings abnormal		
Mucosal pain	1	0
Oedema NEC		
Face oedema	1	0
Localised oedema	1	0
Oedema	1	0
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	12	0
Chest discomfort	66	0
Chest pain	95	0
Discomfort	5	0
Facial pain	3	0
Non-cardiac chest pain	1	0
Pain	612	0
Tenderness	50	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	100	0
Adverse event	1	0
Adverse reaction	2	0
Drug ineffective	1	0
No reaction on previous exposure to drug	3	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	1	0
Vaccination site discomfort	2	0
Vaccination site erythema	9	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	2	0
Vaccination site mass	8	0
Vaccination site pain	52	0
Vaccination site pruritus	1	0
Vaccination site rash	2	0
Vaccination site swelling	6	0
Vaccination site warmth	5	0
General disorders SOC TOTAL	7885	22

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
Hepatic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	19	0
Serum sickness	2	0
Serum sickness-like reaction	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	2	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	12	0
Anaphylactoid reaction	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorder	1	0
Sensitisation	1	0
Immune system disorders SOC TOTAL	45	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	14	1
<i>Breast infections</i>		
Mastitis	1	0
<i>Coronavirus infections</i>		
COVID-19	15	1
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	5	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingivitis	1	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
Eye infection	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Herpes viral infections</i>		
Herpes simplex	2	0
Herpes zoster	3	0
Oral herpes	9	0
<i>Infections NEC</i>		
Abscess	1	0
Abscess limb	1	0
Infection	6	1
Localised infection	2	0
<i>Influenza viral infections</i>		
Influenza	179	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	1
<i>Retroviral infections</i>		
AIDS related complex	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	0
Urosepsis	2	1
<i>Staphylococcal infections</i>		
Furuncle	1	0
Staphylococcal scalded skin syndrome	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	28	0
Rhinitis	1	0
Sinusitis	1	0
Tonsillitis	3	0
<i>Urinary tract infections</i>		
Kidney infection	1	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Sweating fever	28	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Viral rash	1	0
Infections SOC TOTAL	321	5

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Reaction Name	Total	Fatal
Injuries		
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	2	0
Maternal exposure during pregnancy	9	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Non-site specific injuries NEC</i>		
Fall	4	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	17	0
Post procedural complication	2	0
<i>Skin injuries NEC</i>		
Contusion	18	0
<i>Thermal burns</i>		
Thermal burns of eye	1	0
<i>Vaccination related complications</i>		
Vaccination complication	4	0
Injuries SOC TOTAL	61	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation	2	0
Oxygen saturation decreased	9	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
Blood glucose fluctuation	1	0
Blood glucose increased	1	0
Glycosylated haemoglobin increased	1	0
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging brain	1	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio increased	2	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastrointestinal stoma output increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	16	0
Heart rate decreased	3	0
Heart rate increased	48	0
Heart rate irregular	5	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	1	0
<i>Immunology skin tests NEC</i>		
Allergy alert test	2	0
<i>Metabolism tests NEC</i>		
Blood ketone body	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	50	0
Body temperature abnormal	7	0
Body temperature decreased	6	0
Body temperature fluctuation	12	0
Body temperature increased	60	0
Grip strength decreased	2	0
Respiratory rate increased	4	0
Skin temperature	9	0
Weight decreased	3	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	2	0
Urine output decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Blood pressure increased	6	0
Investigations SOC TOTAL	261	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	188	0
Hypophagia	2	0
Increased appetite	2	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	1	1
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	2	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	3	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	4	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketosis	1	0
<i>Total fluid volume decreased</i>		
Dehydration	14	0
Metabolic disorders SOC TOTAL	218	1

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	33	0
Pain in jaw	10	0
Spinal pain	9	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
Periarthritis	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	678	0
Joint noise	2	0
Joint stiffness	10	0
Joint swelling	10	0
Joint warmth	2	0
<i>Muscle pains</i>		
Myalgia	1087	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	21	0
Muscle spasms	57	0
Muscle swelling	1	0
Muscle tightness	1	0
Muscle twitching	10	0
<i>Muscle tone abnormalities</i>		
Trismus	5	0
<i>Muscle weakness conditions</i>		
Muscular weakness	32	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Mobility decreased	3	0
Musculoskeletal stiffness	53	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	222	0
Flank pain	2	0
Limb discomfort	49	0
Musculoskeletal chest pain	9	0
Musculoskeletal discomfort	4	0
Musculoskeletal pain	3	0
Neck pain	69	0
Pain in extremity	441	0
<i>Myopathies</i>		
Myopathy	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Neck mass	1	0
Muscle & tissue disorders SOC TOTAL	2834	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem stroke	1	0
Cerebrovascular accident	4	3
Haemorrhagic stroke	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	15	0
Coordination abnormal	2	0
Dysstasia	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Senile dementia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Consciousness fluctuating	1	0
Depressed level of consciousness	1	0
Lethargy	131	0
Loss of consciousness	7	0
Somnolence	51	0
Syncope	50	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Clumsiness	2	0
Hypokinesia	1	0
Movement disorder	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	5	0
Facial spasm	1	0
<i>Headaches NEC</i>		
Cluster headache	15	0
Cold-stimulus headache	1	0
Exertional headache	1	0
External compression headache	1	0
Headache	2589	0
Sinus headache	19	0
Tension headache	37	0
Thunderclap headache	1	0
Vascular headache	1	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
Memory impairment	3	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	11	0
Mental impairment	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Migraine headaches</i>		
Migraine	183	0
Migraine with aura	6	0
Migraine without aura	2	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	3	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	551	0
Dizziness exertional	1	0
Dizziness postural	59	0
Head discomfort	5	0
Myoclonus	1	0
Neurological symptom	3	0
Presyncope	23	0
Unresponsive to stimuli	4	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	3	0
<i>Olfactory nerve disorders</i>		
Anosmia	6	0
Hyposmia	1	0
Parosmia	6	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	6	0
Hyperaesthesia	16	0
Hypoaesthesia	86	0
Paraesthesia	135	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	2	0
Monoparesis	2	0
Monoplegia	1	0
Paralysis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	4	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	4	0
Febrile convulsion	3	0
Seizure	20	0
Seizure like phenomena	1	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	18	0
Allodynia	4	0
Dysgeusia	49	0
Hypogeusia	1	0
Neuralgia	18	0
Restless legs syndrome	19	0
Sensory disturbance	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Jan-2021
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Reaction Name	Total	Fatal
Nervous system disorders		
Sensory loss	3	0
Taste disorder	12	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	15	0
Sleep deficit	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	5	0
Slow speech	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	4	0
<i>Tremor (excl congenital)</i>		
Intention tremor	1	0
Tremor	219	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	4488	3

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	3	0
Pregnancy conditions SOC TOTAL	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device malfunction events NEC</i>		
Oversensing	1	0
null SOC TOTAL	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Agitation	5	0
Anxiety	11	0
Nervousness	15	0
Tension	6	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	5	0
<i>Confusion and disorientation</i>		
Confusional state	40	0
Disorientation	19	0
<i>Deliria</i>		
Delirium	12	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	4	0
Major depression	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	99	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Irritability	9	0
Mood altered	2	0
<i>Factitious disorders</i>		
Factitious disorder	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	29	0
Hallucination, auditory	1	0
Hallucination, visual	2	0
<i>Increased physical activity levels</i>		
Restlessness	14	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	1	0
Depressed mood	4	0
Negative thoughts	1	0
Sense of a foreshortened future	1	0
Tearfulness	4	0
<i>Mood disorders NEC</i>		
Apathy	2	0
Listless	1	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
Panic reaction	2	0
<i>Parasomnias</i>		
Abnormal dreams	14	0
Nightmare	16	0
Sleep talking	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	2	0
Illusion	1	0
<i>Sexual desire disorders</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	15	0
Somatic symptom disorders		
Conversion disorder	1	0
Stereotypies and automatisms		
Head banging	2	0
Stress disorders		
Hyperarousal	1	0
Suicidal and self-injurious behaviour		
Suicidal ideation	2	0
Thinking disturbances		
Bradyphrenia	3	0
Tachyphrenia	1	0
Thinking abnormal	1	0
Psychiatric disorders SOC TOTAL	357	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Dysuria	3	0
Micturition urgency	3	0
Pollakiuria	11	0
Urinary incontinence	1	0
Urinary retention	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral spasm	1	0
<i>Urinary abnormalities</i>		
Chromaturia	2	0
Urine odour abnormal	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Nocturia	1	0
Polyuria	2	0
Renal pain	29	0
Renal & urinary disorders SOC TOTAL	57	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast mass	1	0
<i>Breast signs and symptoms</i>		
Breast pain	5	0
Breast swelling	1	0
Breast tenderness	1	0
Nipple pain	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	4	0
Menstruation irregular	2	0
Metrorrhagia	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	4	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
Scrotal swelling	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	6	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Vulvovaginal pain	1	0
Reproductive & breast disorders SOC TOTAL	36	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	123	0
Dyspnoea at rest	1	0
Hyperventilation	3	0
Hypopnoea	3	0
Orthopnoea	1	0
Respiration abnormal	3	0
Sleep apnoea syndrome	1	0
Tachypnoea	6	0
<i>Bronchospasm and obstruction</i>		
Asthma	4	0
Bronchospasm	1	0
Chronic obstructive pulmonary disease	1	1
Wheezing	12	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	2	0
<i>Coughing and associated symptoms</i>		
Cough	74	0
Haemoptysis	1	0
Productive cough	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pleuritic pain	1	0
Pulmonary pain	5	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	12	0
<i>Nasal disorders NEC</i>		
Epistaxis	12	0
Nasal dryness	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	6	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	0
<i>Respiratory signs and symptoms NEC</i>		
Respiratory symptom	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	1	0
Lung disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Catarrh	1	0
Dry throat	8	0
Oropharyngeal pain	98	0
Paranasal sinus discomfort	1	0
Rhinalgia	2	0
Rhinorrhoea	28	0
Sinus pain	10	0
Sneezing	9	0
Throat irritation	4	0
Throat tightness	2	0
Respiratory disorders SOC TOTAL	453	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	6	0
Apocrine and eccrine gland disorders		
Cold sweat	60	0
Hyperhidrosis	269	0
Miliaria	4	0
Night sweats	49	0
Bullous conditions		
Blister	8	0
Dermal and epidermal conditions NEC		
Dry skin	2	0
Pain of skin	45	0
Scar pain	1	0
Sensitive skin	18	0
Skin burning sensation	13	0
Skin discolouration	2	0
Skin reaction	5	0
Skin sensitisation	4	0
Skin swelling	1	0
Skin warm	17	0
Yellow skin	2	0
Dermatitis and eczema		
Dermatitis	5	0
Dermatitis allergic	8	1
Eczema asteatotic	1	0
Skin irritation	4	0
Dermatitis ascribed to specific agent		
Drug eruption	1	0
Erythemas		
Erythema	73	0
Exfoliative conditions		
Skin exfoliation	3	0
Lipodystrophies		
Lipohypertrophy	1	0
Photosensitivity and photodermatitis conditions		
Photosensitivity reaction	6	0
Pilar disorders NEC		
Piloerection	2	0
Pruritus NEC		
Pruritus	103	0
Purpura and related conditions		
Petechiae	1	0
Rashes, eruptions and exanthems NEC		
Rash	122	0
Rash erythematous	25	0
Rash macular	6	0
Rash papular	2	0
Rash pruritic	19	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin vasomotor conditions		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Livedo reticularis	2	0
<i>Urticarias</i>		
Urticaria	38	0
Skin disorders SOC TOTAL	930	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	3	0
Immobile	2	0
Sight disability	1	0
Social circumstances SOC TOTAL	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Immunisations</i>		
COVID-19 immunisation	4	0
Immunisation	2	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Muscle therapeutic procedures</i>		
Muscle relaxant therapy	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Hospitalisation	1	0
Injection	1	0
Surgical & medical procedures SOC TOTAL	11	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	2	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
Shock	1	0
<i>Haemorrhages NEC</i>		
Haematoma	2	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	5	0
Flushing	18	0
Hot flush	59	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	20	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	19	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	14	0
<i>Vascular hypotensive disorders</i>		
Hypotension	14	0
Vascular disorders SOC TOTAL	158	0
TOTAL REACTIONS FOR DRUG	21032	34
TOTAL REPORTS	6014	
TOTAL FATAL OUTCOME REPORTS		34