

COVID-19 Moderna Vaccine Analysis Print

All UK spontaneous reports received up to and including 08/12/21 for COVID-19 Moderna vaccine.

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.

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	4	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	3	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	2	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Mast cell activation syndrome	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	201	0
Lymphadenitis	16	0
Lymphadenopathy	1101	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	2	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	6	0
Thrombocytopenia	22	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	1366	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	2	0
Bundle branch block left	1	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	6	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	699	0
<i>Cardiomyopathies</i>		
Congestive cardiomyopathy	1	0
<i>Heart failures NEC</i>		
Cardiac failure	2	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Angina pectoris	31	0
Myocardial infarction	12	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	2	0
Left ventricular dysfunction	2	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
<i>Noninfectious myocarditis</i>		
Hypersensitivity myocarditis	1	0
Myocarditis	111	0
<i>Noninfectious pericarditis</i>		
Pericarditis	63	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	17	0
Bradycardia	9	0
Cardiac fibrillation	1	0
Cardiac flutter	61	0
Extrasystoles	22	0
Tachycardia	206	0
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	14	0
Atrial flutter	7	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	4	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	5	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Ventricular extrasystoles	1	0
Ventricular tachycardia	3	0
Cardiac disorders SOC TOTAL	1301	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	2	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	7	0
Ear discomfort	4	0
Ear disorder	3	0
Ear inflammation	1	0
Ear pain	163	0
Ear swelling	4	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	24	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	22	0
Sudden hearing loss	9	0
<i>Hyperacusia</i>		
Hyperacusis	5	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	13	0
Tinnitus	230	0
Vertigo	188	0
Vertigo labyrinthine	1	0
Vertigo positional	9	0
Ear disorders SOC TOTAL	695	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	6	0
Ovulation delayed	9	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	5	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	2	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	1	0
Vitreous detachment	1	0
Vitreous floaters	8	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	23	0
Eyelid ptosis	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	6	0
<i>Lacrimation disorders</i>		
Dry eye	20	0
Lacrimation increased	9	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	12	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	3	0
Eye pain	187	0
Eye swelling	64	0
Eyelids pruritus	1	0
Ocular discomfort	6	0
Periorbital oedema	2	0
Periorbital swelling	11	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye discharge	1	0
Eye inflammation	4	0
Eye irritation	12	0
Eye pruritus	24	0
Ocular hyperaemia	22	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	10	0
Foreign body sensation in eyes	4	0
Hypoaesthesia eye	3	0
Photophobia	84	0
<i>Optic disc abnormalities NEC</i>		
Optic discs blurred	1	0
Papilloedema	1	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	1	0

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Eye disorders Eye disorders cont'd		
<i>Pupil disorders</i>		
Mydriasis	3	0
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
Astigmatism	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	3	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	4	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual colour distortions</i>		
Cyanopsia	1	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	19	0
Halo vision	1	0
Metamorphopsia	3	0
Photopsia	18	0
Vision blurred	190	0
<i>Visual field disorders</i>		
Visual field defect	3	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	19	0
Blindness transient	4	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	34	0
Eye disorders SOC TOTAL	855	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal pains</i>		
Proctalgia	4	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	3	0
Colitis ulcerative	5	0
Crohn's disease	7	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teething	1	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	3	0
Hyperaesthesia teeth	5	0
Toothache	16	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	668	0
Diarrhoea haemorrhagic	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	74	0
Epigastric discomfort	1	0
Eructation	9	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	7	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	40	0
Flatulence	23	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	210	0
Abdominal pain lower	18	0
Abdominal pain upper	482	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	18	0
Oesophageal pain	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	27	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	26	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
Gastrointestinal disorder	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	89	0
Anal incontinence	3	0
Breath odour	5	0
Dysphagia	22	0
Odynophagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	5	0
Irritable bowel syndrome	9	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	11	0
Gingival swelling	5	0
Noninfective gingivitis	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	10	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	3	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	13	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	2746	0
Regurgitation	1	0
Retching	17	0
Vomiting	1022	0
Vomiting projectile	6	0
<i>Non-site specific gastrointestinal haemorrhages</i>		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	3	0
Haematochezia	6	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
Oral dryness and saliva altered		
Aptyalism	1	0
Dry mouth	64	0
Lip dry	5	0
Saliva altered	2	0
Salivary hypersecretion	7	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Cheilitis	2	0
Enlarged uvula	1	0
Lip blister	2	0
Lip disorder	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	4	0
Oral blood blister	4	0
Oral soft tissue signs and symptoms		
Coating in mouth	2	0
Hypoaesthesia oral	53	0
Lip discolouration	1	0
Lip pain	4	0
Lip pruritus	1	0
Oral discomfort	6	0
Oral mucosal eruption	2	0
Oral mucosal roughening	1	0
Oral pain	19	0
Oral pruritus	1	0
Paraesthesia oral	93	0
Oral soft tissue swelling and oedema		
Lip swelling	107	0
Mouth swelling	10	0
Pancreatic disorders NEC		
Pancreatic failure	1	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	2	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland pain	1	0
Salivary gland enlargements		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	2	0
Stomatitis and ulceration		
Aphthous ulcer	3	0
Lip ulceration	3	0
Mouth ulceration	61	0
Stomatitis	3	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
<i>Tongue disorders</i>		
Glossitis	5	0
Tongue disorder	5	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	19	0
Swollen tongue	53	0
Tongue blistering	2	0
Tongue coated	3	0
Tongue discolouration	3	0
Tongue discomfort	4	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	2	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	6256	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Administration site reaction	2	0
Administration site warmth	1	0
Puncture site bruise	5	0
Puncture site pain	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	7	0
Application site joint erythema	1	0
Application site pain	2	0
Application site pruritus	10	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	345	0
Chronic fatigue syndrome	5	0
Decreased activity	1	0
Fatigue	3643	0
Malaise	685	0
<i>Body temperature altered</i>		
Hypothermia	2	0
<i>Death and sudden death</i>		
Death	9	9
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	3987	1
<i>Feelings and sensations NEC</i>		
Chills	2393	0
Feeling abnormal	310	0
Feeling cold	196	0
Feeling drunk	11	0
Feeling hot	239	0
Feeling jittery	9	0
Feeling of body temperature change	68	0
Hangover	15	0
Hunger	15	0
Sensation of blood flow	1	0
Sensation of foreign body	5	0
Temperature intolerance	18	0
Thirst	73	0
<i>Gait disturbances</i>		
Gait disturbance	21	0
Gait inability	8	0
<i>General signs and symptoms NEC</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Condition aggravated	17	0
Crying	25	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	5	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Illness	371	0
Induration	8	0
Influenza like illness	481	0
Irritability postvaccinal	1	0
Local reaction	22	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1552	0
Screaming	4	0
Secretion discharge	2	0
Swelling	820	0
Swelling face	100	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	111	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site erythema	2	0
Infusion site mass	1	0
Infusion site pain	4	0
Infusion site pruritus	2	0
Infusion site urticaria	2	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	5	0
Injection site bruising	11	0
Injection site cyst	1	0
Injection site discolouration	1	0
Injection site erythema	141	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	5	0
Injection site indentation	2	0
Injection site induration	1	0
Injection site inflammation	10	0
Injection site irritation	3	0
Injection site joint erythema	4	0
Injection site joint pain	1	0
Injection site mass	152	0
Injection site oedema	2	0
Injection site pain	527	0

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General disorders General disorders cont'd		
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	97	0
Injection site rash	171	0
Injection site reaction	16	0
Injection site swelling	72	0
Injection site urticaria	47	0
Injection site vesicles	1	0
Injection site warmth	72	0
Interactions		
Alcohol interaction	1	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	5	0
Mass	19	0
Nodule	6	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	5	0
Localised oedema	4	0
Oedema	7	0
Oedema peripheral	11	0
Pain and discomfort NEC		
Axillary pain	523	0
Chest discomfort	237	0
Chest pain	764	0
Discomfort	87	0
Facial pain	23	0
Inflammatory pain	3	0
Non-cardiac chest pain	2	0
Pain	1668	0
Tenderness	142	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	50	0
Adverse event	1	0
Adverse reaction	4	0
Drug ineffective	10	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	4	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	2	0
Ulcers NEC		
Ulcer	4	0
Vaccination site reactions		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	6	0
Vaccination site bruising	18	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	259	0
Vaccination site haemorrhage	3	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	16	0
Vaccination site inflammation	9	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	62	0
Vaccination site movement impairment	11	0
Vaccination site oedema	1	0
Vaccination site pain	274	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	62	0
Vaccination site rash	129	0
Vaccination site reaction	4	0
Vaccination site scar	1	0
Vaccination site swelling	155	0
Vaccination site urticaria	11	0
Vaccination site vesicles	1	0
Vaccination site warmth	116	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	6	0
General disorders SOC TOTAL	21779	12

Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	5	0
<i>Cholestasis and jaundice</i>		
Jaundice	3	0
Jaundice cholestatic	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	4	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	2	0
Drug-induced liver injury	1	0
Hepatic steatosis	1	0
Immune-mediated hepatitis	1	0
Hepatic disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	2	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	230	0
Infusion related hypersensitivity reaction	12	0
Multiple allergies	2	0
Serum sickness	1	0
Type IV hypersensitivity reaction	13	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	2	0
Allergy to vaccine	10	0
Drug hypersensitivity	8	0
Milk allergy	1	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	48	0
Anaphylactic shock	4	0
Anaphylactoid reaction	3	0
<i>Atopic disorders</i>		
Seasonal allergy	14	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	37	0
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
Sensitisation	3	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	405	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	4	0
Diverticulitis	2	0
Gastroenteritis	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	61	0
Folliculitis	1	0
Injection site cellulitis	2	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	3	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	4	0
<i>Candida infections</i>		
Candida infection	5	0
Oral candidiasis	2	0
Vulvovaginal candidiasis	7	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Meningitis	2	0
<i>Coronavirus infections</i>		
COVID-19	88	0
COVID-19 pneumonia	4	0
Suspected COVID-19	2	0
<i>Coxiella infections</i>		
Q fever	4	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	1	0
Cytomegalovirus infection reactivation	2	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	2	0
Sialoadenitis	1	0
Tooth abscess	1	0
Tooth infection	1	0
<i>Ear infections</i>		
Ear infection	3	0
Labyrinthitis	4	0
Otitis externa	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	9	0
Eye infection	2	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Eyelid boil	1	0
Hordeolum	2	0
Female reproductive tract infections		
Vaginal infection	1	0
Flaviviral infections		
Dengue fever	2	0
Encephalitis Japanese B	1	0
Fungal infections NEC		
Fungal infection	3	0
Fungal skin infection	2	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
Fusobacterium infections		
Necrotising ulcerative gingivostomatitis	1	0
Herpes viral infections		
Eczema herpeticum	2	0
Genital herpes	10	0
Herpes ophthalmic	1	0
Herpes simplex	2	0
Herpes zoster	58	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	52	0
Varicella	2	0
Infections NEC		
Abscess limb	1	0
Abscess rupture	1	0
Infection	65	0
Injection site infection	1	0
Localised infection	16	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	4	0
Vestibulitis	1	0
Wound infection	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	2	0
Infectious transmissions		
Secondary transmission	2	0
Influenza viral infections		
Influenza	356	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	3	0
Lower respiratory tract infection	34	1
Pneumonia	9	1
Male reproductive tract infections		
Epididymitis	1	0
Orchitis	1	0
Mumps viral infections		
Mumps	1	0
Nematode infections		
Enterobiasis	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Eczema infected	1	0
Impetigo	3	0
Pustule	9	0
Pyoderma	1	0
Rash pustular	2	0
Skin infection	9	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	7	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	2	0
Nasopharyngitis	208	0
Peritonsillar abscess	1	0
Pharyngitis	4	0
Rhinitis	5	0
Sinusitis	15	0
Tonsillitis	10	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	6	0
Kidney infection	3	0
Urinary tract infection	21	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Gastroenteritis viral	2	0
Meningitis viral	1	0
Post viral fatigue syndrome	4	0
Sweating fever	35	0
Vestibular neuronitis	1	0
Viral infection	4	0
Viral labyrinthitis	1	0
Viral pharyngitis	3	0
Viral rash	6	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Infections SOC TOTAL	1264	3

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	6	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	9	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	16	0
Foetal exposure during pregnancy	7	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	379	0
Maternal exposure during pregnancy	188	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	3	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat illness	1	0
Heat oedema	4	0
Heat stroke	7	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	8	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	7	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	3	0
Muscle injury	1	0
Muscle strain	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	14	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	4	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Non-site specific injuries NEC</i>		
Arthropod bite	3	0
Bite	1	0
Electric shock	5	0
Fall	24	0
Inflammation of wound	1	0
Injury	3	0
Nervous system injury	1	0
Wound complication	4	0
Wound haemorrhage	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	14	0
Post procedural erythema	1	0
Procedural pain	1	0
<i>Occupational exposures</i>		
Occupational exposure to toxic agent	1	0
<i>Off label uses</i>		
Off label use	12	0
<i>Overdoses NEC</i>		
Overdose	6	0
<i>Peripheral nerve injuries</i>		
Sciatic nerve injury	1	0
<i>Poisoning and toxicity</i>		
Systemic toxicity	1	0
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	62	0
Expired product administered	28	0
Extra dose administered	2	0
Inappropriate schedule of product administration	26	0
Incorrect dose administered	8	0
Incorrect route of product administration	2	0
Poor quality product administered	1	0
Product administered at inappropriate site	3	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Radiation injuries</i>		
Sunburn	12	0
<i>Site specific injuries NEC</i>		
Back injury	1	0
Head injury	7	0
Limb injury	23	0
<i>Skin injuries NEC</i>		
Contusion	218	0
Scar	8	0
Scratch	2	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<i>Spinal cord injuries NEC</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Spinal cord injury cervical	1	0
<i>Stoma complications</i>		
Stoma site discomfort	1	0
Stoma site oedema	1	0
<i>Thermal burns</i>		
Burn oesophageal	1	0
Burns third degree	5	0
Cold burn	1	0
Thermal burn	11	0
Thermal burns of eye	2	0
<i>Thoracic cage fractures and dislocations</i>		
Sternal fracture	1	0
<i>Vaccination related complications</i>		
Vaccination complication	10	0
Injuries SOC TOTAL	1204	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Campylobacter test positive	1	0
<i>Blood counts NEC</i>		
Full blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen consumption decreased	1	0
Oxygen saturation	1	0
Oxygen saturation decreased	9	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose decreased	1	0
Blood glucose increased	3	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
Heart sounds	3	0
<i>Cardiac function diagnostic procedures</i>		
Ejection fraction decreased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Cholesterol analyses</i>		
Low density lipoprotein increased	1	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time abnormal	1	0
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	1	0
Electrocardiogram change	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	8	0
<i>Fertility analyses</i>		
Semen analysis abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
X-ray with contrast upper gastrointestinal tract	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	133	0
Heart rate abnormal	11	0
Heart rate decreased	9	0
Heart rate increased	208	0
Heart rate irregular	40	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate variability decreased	1	0
Investigations NEC		
Blood test abnormal	3	0
Liver function analyses		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase	2	0
Bile output	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	6	0
Liver function test increased	1	0
Mineral and electrolyte analyses		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone scan	1	0
Musculoskeletal and soft tissue tests NEC		
Tender joint count	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Sensory level	1	0
Ophthalmic function diagnostic procedures		
Visual tracking test	1	0
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	59	0
Body temperature abnormal	5	0
Body temperature decreased	5	0
Body temperature fluctuation	15	0
Body temperature increased	62	0
Grip strength	1	0
Grip strength decreased	2	0
Head lag	1	0
Lymph node palpable	3	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	3	0
Respiratory rate decreased	5	0
Respiratory rate increased	7	0
Skin temperature	11	0
Temperature difference of extremities	2	0
Weight decreased	14	0
Weight increased	7	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	1	0
Platelet analyses		
Platelet count decreased	7	0
Protein analyses NEC		
C-reactive protein increased	5	0
Red blood cell analyses		
Haemoglobin E	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Haemoglobin decreased	1	0
Renal function analyses		
Blood creatinine increased	1	0
Reproductive hormone analyses		
Pregnancy test	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	3	0
Therapeutic drug monitoring analyses		
Analgesic drug level	5	0
Thyroid analyses		
Tri-iodothyronine decreased	1	0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase increased	1	0
Urinalysis NEC		
Blood urine present	12	0
Protein urine	1	0
Urinary tract function analyses NEC		
Urine output	3	0
Urine output decreased	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	8	0
Blood pressure diastolic increased	1	0
Blood pressure increased	17	0
Blood pressure measurement	4	0
Blood pressure normal	1	0
Virus identification and serology		
Coronavirus test	4	0
Influenza A virus test	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	4	0
Vitamin analyses		
Blood folate decreased	1	0
White blood cell analyses		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	796	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	237	0
Food craving	2	0
Food refusal	2	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	7	0
Salt craving	1	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
Diabetes mellitus inadequate control	4	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Disorders of purine metabolism</i>		
Gout	12	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	2	0
Gluten sensitivity	1	0
Histamine intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Abnormal weight gain	5	0
Feeding disorder	33	0
Food aversion	4	0
Neonatal insufficient breast milk syndrome	3	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	6	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	8	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	58	0
<i>Total fluid volume increased</i>		
Fluid retention	8	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	416	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	27	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	6	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
<i>Bone disorders NEC</i>		
Jaw cyst	1	0
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	51	0
Bone swelling	1	0
Pain in jaw	59	0
Spinal pain	10	0
<i>Bursal disorders</i>		
Bursitis	9	0
<i>Cartilage disorders</i>		
Costochondritis	13	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
Reynold's syndrome	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0
<i>Joint related disorders NEC</i>		
Joint lock	5	0
Periarthritis	25	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	1441	0
Joint noise	3	0
Joint stiffness	45	0
Joint swelling	42	0
Joint vibration	1	0
Joint warmth	3	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
<i>Muscle infections and inflammations</i>		
Myositis	6	0
<i>Muscle pains</i>		
Fibromyalgia	13	0
Myalgia	1973	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle fatigue	60	0
Muscle haemorrhage	1	0
Muscle spasms	316	0
Muscle swelling	10	0
Muscle tightness	20	0
Muscle twitching	57	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Myosclerosis	1	0
Muscle tone abnormalities		
Muscle rigidity	2	0
Nuchal rigidity	4	0
Trismus	4	0
Muscle weakness conditions		
Muscular weakness	123	0
Musculoskeletal and connective tissue conditions NEC		
Growth retardation	1	0
Mastication disorder	2	0
Mobility decreased	9	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	280	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dupuytren's contracture	1	0
Fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	449	0
Flank pain	12	0
Limb discomfort	252	0
Musculoskeletal chest pain	30	0
Musculoskeletal discomfort	9	0
Musculoskeletal pain	13	0
Neck pain	255	0
Pain in extremity	2528	0
Sacral pain	1	0
Myopathies		
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	4	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	6	0
Soft tissue disorders NEC		
Axillary mass	35	0
Groin pain	14	0
Neck mass	7	0
Soft tissue swelling	1	0
Spondyloarthropathies		
Ankylosing spondylitis	2	0
Arthritis reactive	7	0
Axial spondyloarthritis	1	0
Synovial disorders		
Synovial cyst	4	0
Tendon disorders		
Tendon pain	2	0
Trigger finger	2	0
Trunk deformities		

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Shoulder deformity	1	0
Muscle & tissue disorders SOC TOTAL	8286	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage III	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	3	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	5	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	1	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Neuromas</i>		
Acoustic neuroma	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Skin neoplasms benign</i>		
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	3	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	2	0
Neoplasms SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	3	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	7	0
<i>Autonomic nervous system disorders</i>		
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	2	1
Cerebral infarction	1	0
Cerebrovascular accident	13	1
Haemorrhage intracranial	1	0
Intracranial haematoma	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	2	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	50	0
Coordination abnormal	2	0
Dysstasia	6	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	10	0
Lethargy	317	0
Loss of consciousness	166	0
Somnolence	168	0
Stupor	1	0
Syncope	745	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Clumsiness	2	0
Dyskinesia	8	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	4	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	7	0
Movement disorder	10	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Psychomotor hyperactivity	1	0
Dystonias		
Dystonia	1	0
Eye movement disorders		
IVth nerve paresis	1	0
Facial cranial nerve disorders		
Bell's palsy	47	0
Facial paralysis	27	0
Facial paresis	6	0
Facial spasm	6	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	3	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cluster headache	38	0
Cold-stimulus headache	8	0
Drug withdrawal headache	2	0
Headache	4696	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	61	0
Tension headache	93	0
Thunderclap headache	1	0
Vascular headache	2	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	3	0
Lumbar spinal cord and nerve root disorders		
Sciatica	5	0
Memory loss (excl dementia)		
Amnesia	27	0
Memory impairment	20	0
Transient global amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	12	0
Disturbance in attention	55	0
Mental impairment	6	0
Migraine headaches		
Hemiplegic migraine	3	0
Migraine	481	0
Migraine with aura	31	0
Migraine without aura	2	0
Retinal migraine	3	0
Typical aura without headache	1	0
Vestibular migraine	2	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	2	0
Multiple sclerosis acute and progressive		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Band sensation	1	0
Multiple sclerosis	1	0
Multiple sclerosis relapse	1	0
Muscle tone abnormal		
Drop attacks	1	0
Hypotonia	5	0
Stiff leg syndrome	2	0
Myelitis (incl infective)		
Myelitis transverse	2	0
Narcolepsy and hypersomnia		
Hypersomnia	15	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	4	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Tunnel vision	8	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	2084	0
Dizziness exertional	5	0
Dizziness postural	114	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	42	0
Neurological symptom	5	0
Persistent postural-perceptual dizziness	2	0
Presyncope	176	0
Unresponsive to stimuli	10	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	3	0
Olfactory nerve disorders		
Anosmia	27	0
Parosmia	24	0
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	2	0
Burning sensation	69	0
Formication	3	0
Hemianaesthesia	2	0
Hyperaesthesia	33	0
Hypoaesthesia	408	0
Paraesthesia	578	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	4	0
Hemiplegia	5	0
Monoparesis	12	0
Monoplegia	17	0
Paralysis	17	0
Paresis	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	5	0
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	1	0
Neuralgic amyotrophy	1	0
Neuritis	1	0
Neuropathy peripheral	6	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	14	0
Febrile convulsion	3	0
Partial seizures	3	0
Psychogenic seizure	1	0
Seizure	125	0
Seizure anoxic	1	0
Status epilepticus	27	0
Tonic clonic movements	3	0
Tonic convulsion	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	54	0
Allodynia	1	0
Aura	1	0
Complex regional pain syndrome	1	0
Dysgeusia	138	0
Electric shock sensation	6	0
Hypogeusia	1	0
Neuralgia	68	0
Post herpetic neuralgia	2	0
Restless legs syndrome	28	0
Sensory disturbance	9	0
Sensory loss	19	0
Taste disorder	29	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	3	0
<i>Speech and language abnormalities</i>		
Dysarthria	20	0
Incoherent	8	0
Slow speech	4	0
Speech disorder	11	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	8	0
<i>Tremor (excl congenital)</i>		
Essential tremor	1	0
Head titubation	1	0
Tremor	373	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	3	0
Nervous system disorders SOC TOTAL	11887	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	42	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	3	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	3	0
<i>Maternal complications of labour NEC</i>		
Uterine atony	1	0
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Somatic symptom disorder of pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
Pregnancy conditions SOC TOTAL	67	0

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Device malfunction events NEC</i>		
Thrombosis in device	1	0
<i>Manufacturing materials issues</i>		
Manufacturing materials issue	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	8	0
Suspected product contamination	1	0
<i>Product physical issues</i>		
Product after taste	1	0
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product impurity	1	0
Product quality issue	1	0
<i>Product supply and availability issues</i>		
Product availability issue	2	0
null SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Flat affect	3	0
Inappropriate affect	1	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	17	0
Anxiety	176	0
Nervousness	30	0
Stress	15	0
Tension	7	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	3	0
<i>Behaviour and socialisation disturbances</i>		
Disinhibition	1	0
Paranoia	6	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	32	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	119	0
Disorientation	49	0
<i>Deliria</i>		
Delirium	29	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	61	0
Depression suicidal	4	0
Major depression	1	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	11	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	2	0
Insomnia	232	0
Middle insomnia	11	0
Terminal insomnia	10	0
<i>Dyssomnias</i>		
Poor quality sleep	49	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Anger	10	0
Emotional disorder	15	0
Emotional distress	8	0
Euphoric mood	9	0
Frustration tolerance decreased	1	0
Irritability	38	0
Mood altered	11	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
Fear of death	1	0
Fear of eating	1	0
Fear of injection	6	0
Paruresis	1	0
Phobia	1	0
Phonophobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	12	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	66	0
Hallucination, auditory	4	0
Hallucination, tactile	1	0
Hallucination, visual	1	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	36	0
<i>Mental disorders NEC</i>		
Mental disorder	4	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	68	0
Feeling of despair	3	0
Tearfulness	2	0
<i>Mood alterations with manic symptoms</i>		
Mania	4	0
<i>Mood disorders NEC</i>		
Apathy	7	0
Listless	5	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	1	0
<i>Orgasmic disorders and disturbances</i>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	39	0
Panic reaction	7	0
<i>Parasomnias</i>		
Abnormal dreams	25	0
Nightmare	33	0
Sleep inertia	1	0
Sleep talking	2	0
Sleep terror	3	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Autoscopy	3	0
Derealisation	2	0
Illusion	1	0
Psychiatric elimination disorders		
Enuresis	9	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	1	0
Sexual desire disorders		
Libido decreased	5	0
Libido increased	1	0
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	40	0
Somatic symptom disorders		
Conversion disorder	4	0
Habit cough	4	0
Speech and language usage disturbances		
Disorganised speech	1	0
Speech articulation and rhythm disturbances		
Dysphemia	3	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	2	0
Head banging	1	0
Stress disorders		
Acute stress disorder	1	0
Substance related and addictive disorders		
Alcoholism	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	13	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Thought blocking	1	0
Psychiatric disorders SOC TOTAL	1429	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	1	0
Bladder pain	4	0
Dysuria	7	0
Incontinence	8	0
Micturition urgency	6	0
Pollakiuria	27	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	9	0
Urinary retention	2	0
Urinary straining	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Urinary bladder haemorrhage	2	0
<i>Genitourinary tract infections and inflammations NEC</i>		
Urinary tract inflammation	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	4	0
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	13	0
Haematuria	3	0
Urine abnormality	4	0
Urine odour abnormal	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	5	0
Renal pain	54	0
Renal & urinary disorders SOC TOTAL	163	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	3	0
<i>Breast disorders NEC</i>		
Breast enlargement	3	0
Breast mass	11	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	2	0
Breast discomfort	2	0
Breast oedema	1	0
Breast pain	86	0
Breast swelling	12	0
Breast tenderness	10	0
Nipple pain	1	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	14	0
Nocturnal emission	1	0
Organic erectile dysfunction	8	0
Painful ejaculation	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	1	0
Lactation puerperal increased	2	0
Suppressed lactation	7	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	6	0
Premature menopause	3	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	10	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	320	0
Intermenstrual bleeding	153	0
Menstrual discomfort	2	0
Menstrual disorder	270	0
Menstruation irregular	435	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	14	0
Premenstrual syndrome	13	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	66	0
Hypomenorrhoea	85	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menstruation delayed	559	0
Oligomenorrhoea	20	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	737	0
Menometrorrhagia	6	0
Polymenorrhoea	104	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	7	0
Polycystic ovaries	7	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	15	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	11	0
Pelvic haemorrhage	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile pain	1	0
Penis disorder	3	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	2	0
Genital paraesthesia	1	0
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital odour	1	0
Genital pain	1	0
Pelvic pain	17	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	7	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	3	0
Sexual dysfunction	1	0
<i>Spermatogenesis and semen disorders</i>		
Haematospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	13	0
Testicular swelling	4	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometriosis	11	0
Uterine haemorrhage	8	0
Uterine pain	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	12	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	215	0
Vaginal ulceration	1	0
Vulval haemorrhage	6	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	12	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	3375	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	698	0
Dyspnoea at rest	1	0
Dyspnoea exertional	4	0
Hyperventilation	4	0
Hypopnoea	16	0
Hypoventilation	1	0
Irregular breathing	2	0
Respiration abnormal	11	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	2	0
Tachypnoea	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	43	0
Asthma exercise induced	1	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	1	0
Childhood asthma	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	70	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	2	0
Cough	318	0
Haemoptysis	2	0
Productive cough	21	0
Sputum discoloured	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	2	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	14	0
Pulmonary haemorrhage	1	0
Pulmonary pain	15	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	46	0
Rhinitis allergic	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	114	0
Nasal dryness	2	0
Nasal oedema	2	0
Nasal pruritus	3	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Sinus congestion	10	0
Sinus disorder	3	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	4	0
Pharyngeal swelling	44	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	8	0
<i>Pleural infections and inflammations</i>		
Pleurisy	5	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	3	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	2	0
Pulmonary oedema	4	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	21	0
Pulmonary thrombosis	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	2	0
Respiratory symptom	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Respiratory disorder	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	9	0
Catarrh	1	0
Choking	3	0
Dry throat	17	0
Dysphonia	11	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	4	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	338	0
Paranasal sinus discomfort	6	0
Rhinalgia	4	0
Rhinorrhoea	99	0
Sinus pain	46	0
Sneezing	35	0
Throat irritation	25	0
Throat tightness	40	0
Upper-airway cough syndrome	3	0
Yawning	5	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Respiratory disorders SOC TOTAL	2190	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	28	0
<i>Alopecias</i>		
Alopecia	39	0
Alopecia areata	7	0
Alopecia totalis	2	0
<i>Angioedemas</i>		
Angioedema	30	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	188	0
Hidradenitis	1	0
Hyperhidrosis	628	0
Miliaria	52	0
Night sweats	148	0
<i>Bullous conditions</i>		
Blister	46	0
Blister rupture	1	0
Blood blister	1	0
Dermatitis bullous	1	0
Erythema multiforme	11	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	70	0
Pain of skin	75	0
Papule	20	0
Scab	5	0
Scar pain	3	0
Sensitive skin	92	0
Skin burning sensation	43	0
Skin discolouration	26	0
Skin induration	8	0
Skin lesion	22	0
Skin odour abnormal	1	0
Skin reaction	92	0
Skin sensitisation	10	0
Skin swelling	15	0
Skin tightness	5	0
Skin warm	184	0
Yellow skin	3	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	23	0
Dermatitis allergic	82	0
Dermatitis atopic	11	0
Dermatitis contact	6	0
Dyshidrotic eczema	10	0
Eczema	46	0
Eczema nummular	2	0
Neurodermatitis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin irritation	22	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	887	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	10	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Vitiligo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Lichen planus	2	0
Pityriasis rosea	8	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	16	0
<i>Pilar disorders NEC</i>		
Piloerection	11	0
Trichodynia	1	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	1874	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	19	0
<i>Purpura and related conditions</i>		
Petechiae	16	0
Purpura	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	2138	0
Rash erythematous	835	0
Rash macular	143	0
Rash maculo-papular	2	0
Rash morbilliform	5	0
Rash papular	144	0
Rash pruritic	468	0
Rash vesicular	5	0
<i>Rosaceas</i>		
Rosacea	2	0
<i>Scaly conditions</i>		
Pityriasis	2	0
<i>Sebaceous gland disorders</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Seborrhoea	1	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	4	0
Skin mass	7	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	3	0
Skin ulcer	2	0
Skin cysts and polyps		
Dermal cyst	7	0
Skin dystrophies		
Keloid scar	1	0
Skin wrinkling	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	2	0
Skin hypoplasias and atrophies		
Skin atrophy	2	0
Skin injuries and mechanical dermatoses		
Needle track marks	1	0
Skin vasculitides		
Cutaneous vasculitis	3	0
Vasculitic rash	1	0
Skin vasomotor conditions		
Livedo reticularis	4	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	341	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	2	0
Skin disorders SOC TOTAL	9069	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	1	0
Menopause	5	0
<i>Disability issues</i>		
Bedridden	3	0
Immobile	3	0
Impaired driving ability	2	0
Loss of personal independence in daily activities	1	0
Sight disability	2	0
<i>Employment issues</i>		
Retirement	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	5	0
<i>Social issues NEC</i>		
Social problem	1	0
Social circumstances SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	21	0
Immunisation	33	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	5	0
<i>Therapeutic procedures NEC</i>		
Bed rest	3	0
Botulinum toxin injection	1	0
Hospitalisation	3	0
Injection	22	0
Interchange of vaccine products	3	0
Localised alternating hot and cold therapy	1	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	105	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
Neurogenic shock	1	0
Shock	4	0
<i>Haemorrhages NEC</i>		
Bloody discharge	2	0
Haematoma	4	0
Haemorrhage	168	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	14	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Embolism venous	1	0
Thrombosis	31	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	5	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	3	0
Deep vein thrombosis	16	0
Pelvic venous thrombosis	1	0
Superficial vein thrombosis	1	0
Thrombophlebitis	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	36	0
Hot flush	194	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	61	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	3	0
<i>Site specific vascular disorders NEC</i>		
Pallor	66	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	67	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Hypotension	71	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	790	0
TOTAL REACTIONS FOR DRUG	73833	18
TOTAL REPORTS	22270	
TOTAL FATAL OUTCOME REPORTS		18