

COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 25-Nov-2021
Data Lock Date: 24-Nov-2021 18:30:04

All UK spontaneous reports received up to and including 24/11/2021 for COVID-19 vaccine Moderna

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

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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	3	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	3	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Mast cell activation syndrome	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	160	0
Lymphadenitis	10	0
Lymphadenopathy	908	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	19	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	1117	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	520	0
<i>Cardiomyopathies</i>		
Congestive cardiomyopathy	1	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	25	0
Myocardial infarction	8	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	103	0
<i>Noninfectious pericarditis</i>		
Pericarditis	59	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	15	0
Bradycardia	9	0
Cardiac fibrillation	1	0
Cardiac flutter	44	0
Extrasystoles	18	0
Tachycardia	119	0
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	9	0
Atrial flutter	4	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	2	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	4	0
Ventricular extrasystoles	1	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Ventricular tachycardia	3	0
Cardiac disorders SOC TOTAL	977	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>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	6	0
Ear discomfort	3	0
Ear disorder	2	0
Ear pain	129	0
Ear swelling	2	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>Hearing losses</i>		
Deafness	18	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	18	0
Sudden hearing loss	8	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	202	0
Vertigo	155	0
Vertigo labyrinthine	1	0
Vertigo positional	4	0
Ear disorders SOC TOTAL	577	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>Anterior pituitary hypofunction</i>		
Hypopituitarism	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	8	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	29	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 floaters	7	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	3	0
<i>Eyelid movement disorders</i>		
Blepharospasm	20	0
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	4	0
<i>Lacrimation disorders</i>		
Dry eye	16	0
Lacrimation increased	6	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	9	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye pain	151	0
Eye swelling	49	0
Eyelids pruritus	1	0
Ocular discomfort	4	0
Periorbital oedema	2	0
Periorbital swelling	10	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye inflammation	1	0
Eye irritation	10	0
Eye pruritus	19	0
Ocular hyperaemia	18	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	2	0
Hypoaesthesia eye	2	0
Photophobia	68	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
<i>Pupil disorders</i>		
Mydriasis	3	0

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Eye disorders Eye disorders cont'd		
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
Astigmatism	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
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	16	0
Halo vision	1	0
Metamorphopsia	3	0
Photopsia	13	0
Vision blurred	173	0
<i>Visual field disorders</i>		
Visual field defect	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	18	0
Blindness transient	4	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	27	0
Eye disorders SOC TOTAL	712	0

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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	4	0
Toothache	15	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	552	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	62	0
Epigastric discomfort	1	0
Eructation	7	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	5	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	36	0
Flatulence	19	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	173	0
Abdominal pain lower	15	0
Abdominal pain upper	389	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	14	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	24	0

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Gastrointestinal disorders		
Gastrooesophageal reflux disease	20	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	1	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	76	0
Anal incontinence	3	0
Breath odour	5	0
Dysphagia	20	0
Odynophagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	5	0
Irritable bowel syndrome	8	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	7	0
Gingival swelling	4	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	8	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	3	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	10	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	2287	0
Regurgitation	1	0
Retching	15	0
Vomiting	817	0
Vomiting projectile	4	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	1	0
Haematochezia	5	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
Oral dryness and saliva altered		
Aptyalism	1	0
Dry mouth	55	0
Lip dry	4	0
Saliva altered	2	0
Salivary hypersecretion	6	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Cheilitis	1	0
Enlarged uvula	1	0
Lip blister	2	0
Lip disorder	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	3	0
Oral blood blister	2	0
Oral soft tissue signs and symptoms		
Coating in mouth	2	0
Hypoaesthesia oral	48	0
Lip discolouration	1	0
Lip pain	4	0
Lip pruritus	1	0
Oral discomfort	4	0
Oral mucosal roughening	1	0
Oral pain	13	0
Oral pruritus	1	0
Paraesthesia oral	74	0
Oral soft tissue swelling and oedema		
Lip swelling	93	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	1	0
Stomatitis and ulceration		
Aphthous ulcer	3	0
Lip ulceration	3	0
Mouth ulceration	46	0
Stomatitis	3	0
Tongue disorders		
Glossitis	2	0
Tongue disorder	5	0
Tongue haemorrhage	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Tongue ulceration	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	17	0
Swollen tongue	42	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	3	0
Tongue discomfort	3	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	5166	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	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	6	0
Application site joint erythema	1	0
Application site pain	1	0
Application site pruritus	10	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	4	0
Application site warmth	1	0
Instillation site erythema	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	285	0
Chronic fatigue syndrome	4	0
Fatigue	3004	0
Malaise	528	0
<i>Death and sudden death</i>		
Death	8	8
<i>Febrile disorders</i>		
Pyrexia	3352	1
<i>Feelings and sensations NEC</i>		
Chills	1870	0
Feeling abnormal	263	0
Feeling cold	135	0
Feeling drunk	11	0
Feeling hot	208	0
Feeling jittery	9	0
Feeling of body temperature change	60	0
Hangover	13	0
Hunger	13	0
Sensation of blood flow	1	0
Sensation of foreign body	5	0
Temperature intolerance	17	0
Thirst	56	0
<i>Gait disturbances</i>		
Gait disturbance	18	0
Gait inability	6	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	11	0
Crying	23	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	5	0
Foaming at mouth	2	0

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General disorders General disorders cont'd		
General physical health deterioration	1	0
Illness	290	0
Induration	7	0
Influenza like illness	360	0
Irritability postvaccinal	1	0
Local reaction	21	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1325	0
Screaming	4	0
Secretion discharge	2	0
Swelling	703	0
Swelling face	79	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	97	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site erythema	1	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	10	0
Injection site discolouration	1	0
Injection site erythema	123	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	5	0
Injection site indentation	2	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	127	0
Injection site oedema	2	0
Injection site pain	433	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	91	0
Injection site rash	160	0
Injection site reaction	15	0
Injection site swelling	64	0
Injection site urticaria	45	0
Injection site vesicles	1	0
Injection site warmth	63	0

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General disorders General disorders cont'd		
Interactions		
Alcohol interaction	1	0
Drug interaction	1	0
Mass conditions NEC		
Cyst	4	0
Mass	18	0
Nodule	4	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	3	0
Localised oedema	1	0
Oedema	6	0
Oedema peripheral	8	0
Pain and discomfort NEC		
Axillary pain	443	0
Chest discomfort	203	0
Chest pain	616	0
Discomfort	75	0
Facial pain	20	0
Inflammatory pain	2	0
Non-cardiac chest pain	2	0
Pain	1425	0
Tenderness	122	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	12	0
Adverse event	1	0
Adverse reaction	1	0
Drug ineffective	11	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	3	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		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	5	0
Vaccination site bruising	13	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	232	0
Vaccination site haemorrhage	2	0
Vaccination site hypoaesthesia	4	0
Vaccination site induration	15	0
Vaccination site inflammation	9	0

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General disorders General disorders cont'd		
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 mass	56	0
Vaccination site movement impairment	9	0
Vaccination site oedema	1	0
Vaccination site pain	230	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	57	0
Vaccination site rash	121	0
Vaccination site reaction	4	0
Vaccination site scar	1	0
Vaccination site swelling	143	0
Vaccination site urticaria	10	0
Vaccination site vesicles	1	0
Vaccination site warmth	103	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	5	0
General disorders SOC TOTAL	18081	10

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	5	0
<i>Cholestasis and jaundice</i>		
Jaundice	2	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	3	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	20	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	201	0
Infusion related hypersensitivity reaction	12	0
Multiple allergies	1	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	40	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	33	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	362	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>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	53	0
Folliculitis	1	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
Vaccination site cellulitis	2	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	4	0
<i>Candida infections</i>		
Candida infection	4	0
Oral candidiasis	1	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	72	0
COVID-19 pneumonia	4	0
Suspected COVID-19	1	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
Tooth abscess	1	0
Tooth infection	1	0
<i>Ear infections</i>		
Ear infection	3	0
Labyrinthitis	3	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
Eyelid boil	1	0
Hordeolum	1	0
<i>Female reproductive tract infections</i>		

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Reaction Name	Total	Fatal
Infections Infections cont'd		
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	1
Pneumonia fungal	1	0
Fusobacterium infections		
Necrotising ulcerative gingivostomatitis	1	0
Herpes viral infections		
Eczema herpeticum	1	0
Genital herpes	9	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes zoster	48	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	44	0
Varicella	1	0
Infections NEC		
Abscess limb	1	0
Abscess rupture	1	0
Infection	59	0
Injection site infection	1	0
Localised infection	15	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	4	0
Vestibulitis	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	2	0
Infectious transmissions		
Secondary transmission	2	0
Influenza viral infections		
Influenza	275	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	3	0
Lower respiratory tract infection	23	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
Rabies viral infections		
Rabies	1	1
Rubella viral infections		
Rubella	2	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<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>		
Eczema infected	1	0
Impetigo	2	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	5	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	1	0
Nasopharyngitis	168	0
Peritonsillar abscess	1	0
Pharyngitis	2	0
Rhinitis	3	0
Sinusitis	9	0
Tonsillitis	10	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	5	0
Kidney infection	2	0
Urinary tract infection	18	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Gastroenteritis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	4	0
Sweating fever	31	0
Vestibular neuronitis	1	0
Viral infection	3	0
Viral labyrinthitis	1	0
Viral pharyngitis	2	0
Viral rash	5	0
Infections SOC TOTAL	1040	4

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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	8	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	11	0
Foetal exposure during pregnancy	7	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	368	0
Maternal exposure during pregnancy	181	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	2	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	3	0
Heat stroke	6	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	6	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	9	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	3	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	3	0
Bite	1	0
Electric shock	4	0
Fall	19	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Inflammation of wound	1	0
Injury	3	0
Nervous system injury	1	0
Wound complication	3	0
Wound haemorrhage	1	0
Non-site specific procedural complications		
Injection related reaction	5	0
Post procedural erythema	1	0
Procedural pain	1	0
Occupational exposures		
Occupational exposure to toxic agent	1	0
Off label uses		
Off label use	3	0
Overdoses NEC		
Overdose	6	0
Peripheral nerve injuries		
Sciatic nerve injury	1	0
Poisoning and toxicity		
Toxicity to various agents	1	0
Product administration errors and issues		
Accidental overdose	6	0
Expired product administered	20	0
Inappropriate schedule of product administration	18	0
Incorrect dose administered	2	0
Incorrect route of product administration	2	0
Poor quality product administered	1	0
Product administered at inappropriate site	2	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	1	0
Product dispensing errors and issues		
Product dispensing error	1	0
Radiation injuries		
Sunburn	12	0
Site specific injuries NEC		
Back injury	1	0
Head injury	5	0
Limb injury	18	0
Skin injuries NEC		
Contusion	183	0
Scar	9	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Stoma complications		
Stoma site oedema	1	0
Thermal burns		
Burn oesophageal	1	0
Burns third degree	1	0
Cold burn	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Thermal burn	10	0
Thermal burns of eye	1	0
Thoracic cage fractures and dislocations		
Sternal fracture	1	0
Vaccination related complications		
Vaccination complication	6	0
Injuries SOC TOTAL	1002	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 decreased	6	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>		
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	7	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>Heart rate and pulse investigations</i>		
Heart rate	109	0
Heart rate abnormal	9	0
Heart rate decreased	7	0
Heart rate increased	166	0
Heart rate irregular	31	0
Heart rate variability decreased	1	0
<i>Investigations NEC</i>		
Blood test abnormal	3	0
<i>Liver function analyses</i>		

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase	2	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 abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	48	0
Body temperature abnormal	3	0
Body temperature decreased	3	0
Body temperature fluctuation	12	0
Body temperature increased	49	0
Grip strength	1	0
Grip strength decreased	1	0
Head lag	1	0
Lymph node palpable	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	2	0
Respiratory rate decreased	3	0
Respiratory rate increased	6	0
Skin temperature	9	0
Temperature difference of extremities	1	0
Weight decreased	14	0
Weight increased	6	0
Pituitary analyses anterior		
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
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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	2	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	4	0
<i>Tissue enzyme analyses NEC</i>		
Blood lactate dehydrogenase increased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	8	0
Protein urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	3	0
Urine output decreased	1	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	13	0
Blood pressure measurement	3	0
<i>Virus identification and serology</i>		
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	2	0
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
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	648	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	191	0
Food craving	2	0
Food refusal	1	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	6	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
Diabetes mellitus inadequate control	2	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	10	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
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	5	0
Feeding disorder	27	0
Food aversion	4	0
Neonatal insufficient breast milk syndrome	3	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	3	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	5	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	50	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	340	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	21	0
Arthritis enteropathic	1	0
Arthropathy	5	0
Autoimmune arthritis	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	39	0
Bone swelling	1	0
Pain in jaw	47	0
Spinal pain	8	0
<i>Bursal disorders</i>		
Bursitis	7	0
<i>Cartilage disorders</i>		
Costochondritis	13	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	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	4	0
Periarthritis	21	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	1093	0
Joint noise	3	0
Joint stiffness	36	0
Joint swelling	35	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	12	0
Myalgia	1619	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle fatigue	52	0
Muscle haemorrhage	1	0
Muscle spasms	280	0
Muscle swelling	9	0
Muscle tightness	18	0
Muscle twitching	51	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle rigidity	2	0
Nuchal rigidity	3	0
Trismus	4	0
Muscle weakness conditions		
Muscular weakness	101	0
Musculoskeletal and connective tissue conditions NEC		
Growth retardation	1	0
Mastication disorder	2	0
Mobility decreased	8	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	242	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	371	0
Flank pain	9	0
Limb discomfort	218	0
Musculoskeletal chest pain	23	0
Musculoskeletal discomfort	9	0
Musculoskeletal pain	9	0
Neck pain	194	0
Pain in extremity	2128	0
Sacral pain	1	0
Myopathies		
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	3	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	4	0
Soft tissue disorders NEC		
Axillary mass	26	0
Groin pain	12	0
Neck mass	5	0
Purple glove syndrome	1	0
Soft tissue swelling	1	0
Spondyloarthropathies		
Ankylosing spondylitis	2	0
Arthritis reactive	5	0
Axial spondyloarthritis	1	0
Synovial disorders		
Synovial cyst	4	0
Tendon disorders		
Tendon pain	1	0
Trigger finger	2	0
Trunk deformities		
Shoulder deformity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders cont'd		
Muscle & tissue disorders SOC TOTAL	6804	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>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
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	27	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	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	12	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	1	0
Balance disorder	34	0
Coordination abnormal	1	0
Dysstasia	4	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	8	0
Lethargy	255	0
Loss of consciousness	140	0
Somnolence	147	0
Stupor	1	0
Syncope	651	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	6	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	3	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	6	0
Movement disorder	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	42	0
Facial paralysis	25	0
Facial paresis	4	0
Facial spasm	4	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	31	0
Cold-stimulus headache	4	0
Drug withdrawal headache	2	0
Headache	3785	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	41	0
Tension headache	79	0
Thunderclap headache	1	0
Vascular headache	2	0
<i>Increased intracranial pressure disorders</i>		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	3	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	4	0
<i>Memory loss (excl dementia)</i>		
Amnesia	23	0
Memory impairment	19	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	11	0
Disturbance in attention	50	0
Mental impairment	6	0
<i>Migraine headaches</i>		
Hemiplegic migraine	3	0
Migraine	403	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
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Multiple sclerosis	1	0
Muscle tone abnormal		
Hypotonia	4	0
Stiff leg syndrome	2	0
Myelitis (incl infective)		
Myelitis transverse	2	0
Narcolepsy and hypersomnia		
Hypersomnia	12	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Tunnel vision	7	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	1798	0
Dizziness exertional	5	0
Dizziness postural	86	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	37	0
Neurological symptom	5	0
Persistent postural-perceptual dizziness	1	0
Presyncope	154	0
Unresponsive to stimuli	9	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	3	0
Olfactory nerve disorders		
Anosmia	18	0
Parosmia	17	0
Optic nerve disorders NEC		
Optic neuritis	2	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	1	0
Burning sensation	62	0
Formication	3	0
Hemianaesthesia	2	0
Hyperaesthesia	32	0
Hypoaesthesia	361	0
Paraesthesia	511	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	4	0
Hemiplegia	5	0
Monoparesis	10	0
Monoplegia	15	0
Paralysis	14	0
Paresis	2	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	1	0
Reduced facial expression	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	1	0
Neuralgic amyotrophy	1	0
Neuritis	1	0
Neuropathy peripheral	5	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	8	0
Febrile convulsion	3	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	107	0
Seizure anoxic	1	0
Status epilepticus	25	0
Tonic clonic movements	3	0
Tonic convulsion	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	39	0
Allodynia	1	0
Complex regional pain syndrome	1	0
Dysgeusia	115	0
Electric shock sensation	5	0
Hypogeusia	1	0
Neuralgia	54	0
Post herpetic neuralgia	2	0
Restless legs syndrome	26	0
Sensory disturbance	8	0
Sensory loss	13	0
Taste disorder	25	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	19	0
Incoherent	7	0
Slow speech	3	0
Speech disorder	10	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	6	0
<i>Tremor (excl congenital)</i>		
Tremor	271	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	3	0
Nervous system disorders SOC TOTAL	9883	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	39	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
Morning sickness	1	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
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	66	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
<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
total SOC TOTAL	18	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	15	0
Anxiety	160	0
Nervousness	26	0
Stress	14	0
Tension	7	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	4	0
<i>Behaviour and socialisation disturbances</i>		
Disinhibition	1	0
Paranoia	5	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	28	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	99	0
Disorientation	39	0
<i>Deliria</i>		
Delirium	17	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	51	0
Depression suicidal	3	0
Major depression	1	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	10	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	2	0
Insomnia	198	0
Middle insomnia	10	0
Terminal insomnia	10	0
<i>Dyssomnias</i>		
Poor quality sleep	41	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	7	0
Emotional disorder	14	0
Emotional distress	8	0
Euphoric mood	7	0
Irritability	36	0
Mood altered	8	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
Fear of death	1	0
Fear of injection	6	0
Paruresis	1	0
Phobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	12	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	58	0
Hallucination, auditory	3	0
Hallucination, tactile	1	0
Hallucination, visual	1	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	32	0
<i>Mental disorders NEC</i>		
Mental disorder	3	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	58	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	6	0
Listless	3	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	37	0
Panic reaction	7	0
<i>Parasomnias</i>		
Abnormal dreams	21	0
Nightmare	24	0
Sleep inertia	1	0
Sleep talking	2	0
Sleep terror	3	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	3	0
Derealisation	2	0
Illusion	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Psychiatric elimination disorders</i>		
Enuresis	8	0
<i>Psychiatric symptoms NEC</i>		
Psychiatric symptom	1	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	1	0
<i>Sexual desire disorders</i>		
Libido decreased	4	0
Libido increased	1	0
Loss of libido	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	28	0
<i>Somatic symptom disorders</i>		
Conversion disorder	4	0
Habit cough	4	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	3	0
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	2	0
Head banging	1	0
<i>Substance related and addictive disorders</i>		
Alcoholism	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	9	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	1228	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	4	0
Dysuria	6	0
Incontinence	5	0
Micturition urgency	4	0
Pollakiuria	19	0
Urethral pain	1	0
Urinary incontinence	8	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>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	10	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	47	0
Renal & urinary disorders SOC TOTAL	134	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	10	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	1	0
Breast discomfort	1	0
Breast oedema	1	0
Breast pain	68	0
Breast swelling	9	0
Breast tenderness	9	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	11	0
Nocturnal emission	1	0
Organic erectile dysfunction	6	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	8	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	305	0
Intermenstrual bleeding	149	0
Menstrual discomfort	2	0
Menstrual disorder	256	0
Menstruation irregular	420	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	13	0
Premenstrual syndrome	13	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	61	0
Hypomenorrhoea	83	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menstruation delayed	545	0
Oligomenorrhoea	20	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	706	0
Menometrorrhagia	5	0
Polymenorrhoea	101	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	7	0
Polycystic ovaries	5	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	10	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	15	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	4	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	3	0
Sexual dysfunction	1	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	10	0
Testicular swelling	4	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometriosis	10	0
Uterine haemorrhage	7	0
Uterine pain	3	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	202	0
Vaginal ulceration	1	0
Vulval haemorrhage	6	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	11	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	3209	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	549	0
Dyspnoea exertional	4	0
Hyperventilation	4	0
Hypopnoea	13	0
Hypoventilation	1	0
Irregular breathing	2	0
Respiration abnormal	9	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	2	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	35	0
Asthma exercise induced	1	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Childhood asthma	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	51	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	254	0
Productive cough	18	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	12	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	31	0
<i>Nasal disorders NEC</i>		
Epistaxis	92	0
Nasal oedema	1	0
Nasal pruritus	3	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	1	0
Sinus congestion	6	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	4	0
Pharyngeal swelling	39	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	3	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	19	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
Respiratory symptom	2	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	6	0
Catarrh	1	0
Choking	3	0
Dry throat	15	0
Dysphonia	9	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	3	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	282	0
Paranasal sinus discomfort	5	0
Rhinalgia	2	0
Rhinorrhoea	74	0
Sinus pain	33	0
Sneezing	22	0
Throat irritation	21	0
Throat tightness	35	0
Upper-airway cough syndrome	1	0
Yawning	5	0
Respiratory disorders SOC TOTAL	1744	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	28	0
<i>Alopecias</i>		
Alopecia	34	0
Alopecia areata	5	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	25	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	167	0
Hidradenitis	1	0
Hyperhidrosis	537	0
Miliaria	47	0
Night sweats	116	0
<i>Bullous conditions</i>		
Blister	42	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	61	0
Pain of skin	60	0
Papule	20	0
Scab	5	0
Scar pain	2	0
Sensitive skin	83	0
Skin burning sensation	42	0
Skin discolouration	20	0
Skin induration	6	0
Skin lesion	22	0
Skin odour abnormal	1	0
Skin reaction	85	0
Skin sensitisation	9	0
Skin swelling	14	0
Skin tightness	4	0
Skin warm	168	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	20	0
Dermatitis allergic	76	0
Dermatitis atopic	11	0
Dermatitis contact	5	0
Dyshidrotic eczema	9	0
Eczema	45	0
Eczema nummular	2	0
Neurodermatitis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin irritation	18	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	792	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	9	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	13	0
<i>Pilar disorders NEC</i>		
Piloerection	9	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	1674	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	16	0
<i>Purpura and related conditions</i>		
Petechiae	14	0
Purpura	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	1947	0
Rash erythematous	766	0
Rash macular	127	0
Rash maculo-papular	2	0
Rash morbilliform	5	0
Rash papular	133	0
Rash pruritic	430	0
Rash vesicular	5	0
<i>Rosaceas</i>		
Rosacea	2	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	3	0
Skin mass	4	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	1	0
Skin ulcer	2	0
<i>Skin cysts and polyps</i>		
Dermal cyst	6	0
<i>Skin dystrophies</i>		
Keloid scar	1	0
Skin wrinkling	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	2	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	2	0
Vasculitic rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	3	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	300	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	2	0
Skin disorders SOC TOTAL	8133	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	2	0
Impaired driving ability	1	0
Loss of personal independence in daily activities	1	0
Sight disability	1	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	23	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>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	17	0
Immunisation	23	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	4	0
<i>Therapeutic procedures NEC</i>		
Bed rest	2	0
Botulinum toxin injection	1	0
Hospitalisation	3	0
Injection	19	0
Interchange of vaccine products	2	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	83	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>		
Neurogenic shock	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	4	0
Haemorrhage	156	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	11	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	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	3	0
Deep vein thrombosis	11	0
Superficial vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	31	0
Hot flush	177	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	46	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	64	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	52	0
Prehypertension	1	0
White coat hypertension	1	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Hypotension	62	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	696	0
TOTAL REACTIONS FOR DRUG	62126	18
TOTAL REPORTS	19101	
TOTAL FATAL OUTCOME REPORTS		18