

COVID-19 Moderna Vaccine Analysis Print

All UK spontaneous reports received up to and including 18/05/2022 for Moderna COVID-19 vaccine.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean 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 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: 20-May-2022

Data Lock Date: 18-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	16	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	7	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Abnormal clotting factor	1	0
Antiphospholipid syndrome	3	0
Coagulopathy	3	0
Hypercoagulation	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	2	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Mast cell activation syndrome	2	0
Mastocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	348	0
Lymph node ulcer	1	0
Lymphadenitis	27	0
Lymphadenopathy	2063	0
Lymphatic disorder	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	3	0
<i>Platelet disorders NEC</i>		
Platelet disorder	1	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Spleen disorders</i>		
Splenic infarction	1	0
Splenic vein thrombosis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	10	0
Thrombocytopenia	33	0
Thrombocytopenic purpura	2	0
Blood disorders SOC TOTAL	2537	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	4	0
Bundle branch block left	1	0
Bundle branch block right	2	0
Sinoatrial block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	19	0
Cardiac dysfunction	2	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	3	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	5	0
Palpitations	1737	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
Toxic cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	1
Coronary artery disease	1	0
Coronary artery occlusion	1	0
Coronary artery stenosis	1	0
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	7	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	1	0
Acute myocardial infarction	4	0
Angina pectoris	67	0
Angina unstable	3	0
Myocardial infarction	40	2
Myocardial ischaemia	1	0
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	7	0
Left ventricular dilatation	1	0
Left ventricular dysfunction	4	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	2	0
Myocardial injury	1	0
Myocardial oedema	2	0
<i>Noninfectious myocarditis</i>		
Hypersensitivity myocarditis	1	0
Myocarditis	194	0

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Cardiac disorders Cardiac disorders cont'd		
Myopericarditis	28	0
Noninfectious pericarditis		
Pericarditis	131	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Pericardial effusion	3	0
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	31	0
Bradycardia	15	0
Cardiac fibrillation	1	0
Cardiac flutter	139	0
Extrasystoles	55	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	2	0
Tachyarrhythmia	3	0
Tachycardia	760	1
Tachycardia foetal	1	0
Supraventricular arrhythmias		
Atrial fibrillation	46	0
Atrial flutter	12	0
Atrial tachycardia	2	0
Sinus arrhythmia	2	0
Sinus tachycardia	11	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	6	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	18	6
Ventricular extrasystoles	4	0
Ventricular tachycardia	6	0
Cardiac disorders SOC TOTAL	3408	11

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	3	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Gene mutations and other alterations NEC</i>		
Hereditary angioedema	1	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
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	1	0
Congenital disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	8	0
Ear discomfort	9	0
Ear disorder	5	0
Ear inflammation	1	0
Ear pain	305	0
Ear swelling	6	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	55	0
Deafness neurosensory	2	0
Deafness transitory	1	0
Deafness unilateral	8	0
Hypoacusis	42	0
Sudden hearing loss	13	0
<i>Hyperacusia</i>		
Hyperacusis	10	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
Vestibular disorder	1	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	4	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	19	0
Tinnitus	451	0
Vertigo	310	0
Vertigo labyrinthine	2	0
Vertigo positional	15	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	1276	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	2	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	5	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	7	0
Ovulation delayed	11	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	1	0
<i>Hypoparathyroid disorders</i>		
Hypoparathyroidism	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Polyglandular endocrine disorders</i>		
Polyglandular disorder	1	0
<i>Thyroid disorders NEC</i>		
Goitre	6	0
Thyroid disorder	1	0
Thyroid pain	2	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	4	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	5	0
Endocrine disorders SOC TOTAL	57	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	4	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	2	0
Vitreous floaters	19	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	2	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	9	0
<i>Corneal infections, oedemas and inflammations</i>		
Ulcerative keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	35	0
Eyelid ptosis	4	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	2	0
Iritis	2	0
Uveitis	11	0
<i>Lacrimation disorders</i>		
Dry eye	37	0
Lacrimation increased	17	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	2	0
Erythema of eyelid	2	0
Eyelid cyst	1	0
Eyelid irritation	2	0
Eyelid oedema	2	0
Eyelid rash	2	0
Swelling of eyelid	33	0
<i>Lid, lash and lacrimal structural disorders</i>		
Lagophthalmos	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
Eye haemorrhage	4	0
<i>Ocular disorders NEC</i>		
Eye disorder	5	0
Eye oedema	1	0
Eye pain	350	0
Eye swelling	132	0
Eyelid disorder	3	0
Eyelids pruritus	3	0
Ocular discomfort	15	0
Periorbital oedema	3	0
Periorbital swelling	21	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	3	0
Eye discharge	2	0
Eye inflammation	8	0
Eye irritation	20	0
Eye pruritus	39	0
Limbal swelling	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Ocular hyperaemia	46	0
Ocular nerve and muscle disorders		
Eye movement disorder	7	0
Gaze palsy	1	0
Ophthalmoplegia	1	0
Ocular sensation disorders		
Abnormal sensation in eye	2	0
Asthenopia	30	0
Foreign body sensation in eyes	7	0
Hypoaesthesia eye	6	0
Photophobia	132	0
Optic disc abnormalities NEC		
Optic discs blurred	1	0
Papilloedema	1	0
Optic nerve bleeding and vascular disorders		
Optic ischaemic neuropathy	1	0
Orbital infections, inflammations and irritations		
Orbital myositis	2	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	2	0
Pupil disorders		
Mydriasis	5	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Astigmatism	3	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	10	0
Retinal structural change, deposit and degeneration		
Macular hole	1	0
Retinal detachment	1	0
Retinal, choroid and vitreous infections and inflammations		
Retinal oedema	1	0
Retinopathies NEC		
Acute macular neuroretinopathy	1	0
Central serous chorioretinopathy	4	0
Serous retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	5	0
Scleral structural change, deposit and degeneration		
Scleral disorder	1	0
Structural change, deposit and degeneration of eye NEC		
Exophthalmos	2	0
Visual colour distortions		
Cyanopsia	1	0
Xanthopsia	2	0
Visual disorders NEC		
Diplopia	34	0
Halo vision	4	0
Metamorphopsia	5	0
Photopsia	32	0
Scintillating scotoma	1	0

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Eye disorders Eye disorders cont'd		
Vision blurred	317	0
Visual field disorders		
Visual field defect	5	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	1	0
Blindness	40	0
Blindness transient	7	0
Blindness unilateral	2	0
Night blindness	1	0
Visual acuity reduced	3	0
Visual impairment	63	0
Eye disorders SOC TOTAL	1597	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	4	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	8	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anal rash	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	6	0
Colitis ischaemic	1	0
Colitis ulcerative	9	0
Crohn's disease	8	0
Inflammatory bowel disease	7	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teething	2	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Dental paraesthesia	5	0
Hyperaesthesia teeth	6	0
Toothache	37	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1219	0
Diarrhoea haemorrhagic	6	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	161	0
Epigastric discomfort	4	0
Eructation	19	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	10	0
Faeces soft	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	81	0
Flatulence	42	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	11	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	348	0
Abdominal pain lower	25	0
Abdominal pain upper	905	0
Abdominal rigidity	3	0
Abdominal tenderness	5	0
Gastrointestinal pain	40	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	44	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	39	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	2	0
Functional gastrointestinal disorder	3	0
Gastric disorder	2	0
Gastrointestinal disorder	3	0
Lymphoid hyperplasia of intestine	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	3	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	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	183	0
Acute abdomen	1	0
Anal incontinence	3	0
Breath odour	8	0
Dysphagia	35	0
Odynophagia	8	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	11	0
Irritable bowel syndrome	19	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	2	0
Mesenteric vein thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	22	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gingival swelling	8	0
Noninfective gingivitis	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	14	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	6	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	19	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	4849	0
Regurgitation	1	0
Retching	33	0
Vomiting	1857	0
Vomiting projectile	26	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	3	0
Haematemesis	8	0
Haematochezia	17	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
<i>Oesophageal disorders NEC</i>		
Oesophageal disorder	1	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	112	0
Lip dry	11	0
Saliva altered	2	0
Salivary hypersecretion	12	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	3	0
Cheilitis	4	0
Enlarged uvula	1	0
Lip blister	3	0
Lip disorder	1	0
Oral disorder	1	0
Uvulitis	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	4	0
Oral blood blister	4	0
<i>Oral soft tissue signs and symptoms</i>		
Coating in mouth	2	0
Hypoaesthesia oral	93	0
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	12	0
Lip pruritus	3	0
Oral discomfort	12	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral mucosal blistering	2	0
Oral mucosal eruption	3	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	37	0
Oral pruritus	2	0
Paraesthesia oral	130	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	1	0
Lip swelling	224	0
Mouth swelling	24	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	3	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland mass	1	0
Salivary gland pain	3	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	3	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	4	0
Lip ulceration	4	0
Mouth ulceration	101	0
Stomatitis	6	0
<i>Tongue disorders</i>		
Glossitis	8	0
Tongue disorder	11	0
Tongue haemorrhage	1	0
Tongue ulceration	5	0
<i>Tongue signs and symptoms</i>		
Glossodynia	31	0
Stiff tongue	1	0
Swollen tongue	95	0
Tongue blistering	3	0
Tongue coated	5	0
Tongue discolouration	3	0
Tongue discomfort	7	0
Tongue dry	3	0
Tongue eruption	1	0
Tongue exfoliation	1	0
Tongue movement disturbance	1	0
Tongue oedema	3	0
Tongue pruritus	1	0
Tongue spasm	1	0
<i>Tooth missing</i>		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	11279	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	2	0
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	6	0
Puncture site pain	4	0
Vessel puncture site bruise	2	0
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	11	0
Application site inflammation	1	0
Application site joint erythema	1	0
Application site pain	4	0
Application site pruritus	10	0
Application site rash	1	0
Application site reaction	1	0
Application site swelling	3	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	5	0
<i>Asthenic conditions</i>		
Asthenia	643	0
Chronic fatigue syndrome	9	0
Decreased activity	1	0
Fatigue	6792	0
Malaise	1192	0
Sluggishness	2	0
<i>Body temperature altered</i>		
Hyperthermia	2	0
Hypothermia	5	0
Temperature regulation disorder	3	0
<i>Complications associated with device NEC</i>		
Complication associated with device	1	0
Injury associated with device	1	0
<i>Death and sudden death</i>		
Cardiac death	2	2
Death	22	22
Sudden cardiac death	1	1
Sudden death	2	2
<i>Febrile disorders</i>		
Pyrexia	6972	1
<i>Feelings and sensations NEC</i>		
Chills	4256	0
Feeling abnormal	469	0
Feeling cold	439	0

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General disorders General disorders cont'd		
Feeling drunk	17	0
Feeling hot	383	0
Feeling jittery	12	0
Feeling of body temperature change	132	0
Hangover	21	0
Hunger	18	0
Sensation of blood flow	1	0
Sensation of foreign body	8	0
Temperature intolerance	22	0
Thirst	128	0
Thirst decreased	1	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	41	0
Gait inability	25	0
Loss of control of legs	4	0
General signs and symptoms NEC		
Condition aggravated	46	0
Crepitations	1	0
Crying	38	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	18	0
Foaming at mouth	2	0
General physical health deterioration	4	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	717	0
Induration	11	0
Influenza like illness	837	0
Irritability postvaccinal	1	0
Local reaction	28	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2241	0
Pre-existing disease	1	0
Screaming	8	0
Secretion discharge	2	0
Swelling	1262	0
Swelling face	214	0
Implant and catheter site reactions		
Catheter site related reaction	1	0
Implant site warmth	3	0
Inflammations		
Granuloma	1	0
Inflammation	208	0
Scar inflammation	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site erythema	2	0
Infusion site mass	1	0
Infusion site pain	5	0
Infusion site pruritus	2	0
Infusion site urticaria	5	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	10	0
Injection site bruising	15	0
Injection site cyst	1	0
Injection site dermatitis	1	0
Injection site discolouration	1	0
Injection site erythema	221	0
Injection site haemorrhage	4	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	19	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	2	0
Injection site mass	212	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site oedema	6	0
Injection site pain	895	0
Injection site paraesthesia	2	0
Injection site plaque	1	0
Injection site pruritus	141	0
Injection site rash	211	0
Injection site reaction	25	0
Injection site swelling	119	0
Injection site urticaria	58	0
Injection site vesicles	3	0
Injection site warmth	103	0
Interactions		
Alcohol interaction	2	0
Drug interaction	3	0
Mass conditions NEC		
Cyst	9	0
Mass	31	0
Nodule	6	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	2	0
Mucosal inflammation	1	0
Mucosal pain	1	0
Oedema mucosal	1	0
Polyp	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	10	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Localised oedema	7	0
Oedema	18	0
Oedema peripheral	15	0
<i>Pain and discomfort NEC</i>		
Axillary pain	919	0
Chest discomfort	473	0
Chest pain	1834	0
Discomfort	145	0
Facial discomfort	1	0
Facial pain	46	0
Hernia pain	1	0
Inflammatory pain	6	0
Non-cardiac chest pain	3	0
Pain	2805	0
Tenderness	207	0
Visceral pain	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	80	0
Adverse reaction	1	0
Drug ineffective	22	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	1	0
Therapeutic response changed	1	0
Therapeutic response unexpected	3	0
Treatment failure	1	0
Vaccination failure	10	0
<i>Ulcers NEC</i>		
Ulcer	5	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	15	0
Vaccination site bruising	28	0
Vaccination site discolouration	2	0
Vaccination site discomfort	9	0
Vaccination site eczema	1	0
Vaccination site erythema	311	0
Vaccination site haemorrhage	6	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	23	0
Vaccination site inflammation	20	0
Vaccination site irritation	3	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0
Vaccination site macule	1	0
Vaccination site mass	84	0
Vaccination site movement impairment	22	0
Vaccination site oedema	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site pain	422	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	75	0
Vaccination site rash	152	0
Vaccination site reaction	8	0
Vaccination site scar	1	0
Vaccination site swelling	211	0
Vaccination site urticaria	14	0
Vaccination site vesicles	3	0
Vaccination site warmth	146	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Rebound effect	1	0
Withdrawal syndrome	7	0
General disorders SOC TOTAL	37717	29

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	5	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Jaundice	5	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
Hypertransaminasaemia	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Acute on chronic liver failure	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	13	0
Liver tenderness	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	3	0
Hepatic steatosis	1	0
Hepatitis	2	0
Immune-mediated hepatitis	1	0
Liver injury	4	0
Hepatic disorders SOC TOTAL	47	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	362	0
Infusion related hypersensitivity reaction	13	0
Multiple allergies	4	0
Serum sickness	3	0
Serum sickness-like reaction	1	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	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	14	0
Drug hypersensitivity	15	0
Food allergy	4	0
Milk allergy	1	0
Perfume sensitivity	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	74	0
Anaphylactic shock	8	0
Anaphylactoid reaction	11	0
<i>Atopic disorders</i>		
Seasonal allergy	16	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	52	0
Immune system disorder	4	0
Immune-mediated adverse reaction	1	0
Immunisation reaction	22	0
Sensitisation	4	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	2	0
Immune system disorders SOC TOTAL	644	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	10	0
Appendicitis perforated	1	0
Diverticulitis	5	0
Dysentery	1	0
Gastroenteritis	6	0
Peritonitis	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Arthritis bacterial	1	0
Bacterial infection	3	0
Cellulitis	82	0
Folliculitis	1	0
Injection site cellulitis	2	0
Meningitis bacterial	1	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	4	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
Osteomyelitis	1	0
<i>Borrelial infections</i>		
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	2	0
Mastitis	10	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	8	0
Oral candidiasis	6	0
Vulvovaginal candidiasis	10	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Encephalitis	4	0
Meningitis	6	0
Meningitis aseptic	1	0
Myelitis	1	0
<i>Chlamydial infections</i>		
Eye infection chlamydial	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	1	0
COVID-19	397	0
COVID-19 pneumonia	6	0
Coronavirus infection	1	0
Post-acute COVID-19 syndrome	5	0
Suspected COVID-19	5	0
<i>Coxiella infections</i>		
Q fever	8	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Cytomegalovirus infection reactivation	2	0
Pneumonia cytomegaloviral	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	2	0
Oral infection	1	0
Sialoadenitis	2	0
Tooth abscess	2	0
Tooth infection	2	0
<i>Ear infections</i>		
Ear infection	10	0
Labyrinthitis	15	0
Otitis externa	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
Lice infestation	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Chorioretinitis	1	0
Conjunctivitis	13	0
Eye infection	4	0
Eyelid boil	1	0
Hordeolum	5	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0
<i>Flaviviral infections</i>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<i>Fungal infections NEC</i>		
Fungal infection	4	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Helicobacter infections</i>		
Helicobacter infection	1	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	1	0
Genital herpes	15	0
Herpes ophthalmic	1	0
Herpes simplex	8	0
Herpes simplex reactivation	1	0
Herpes virus infection	1	0
Herpes zoster	129	0
Herpes zoster oticus	3	0
Nasal herpes	1	0
Ophthalmic herpes simplex	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Ophthalmic herpes zoster	1	0
Oral herpes	96	0
Varicella	3	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	2	0
Abscess limb	2	0
Abscess rupture	1	0
Empyema	1	1
Groin infection	1	0
Infection	95	0
Injection site infection	1	0
Localised infection	19	0
Lymph gland infection	2	0
Lymph node abscess	3	0
Respiratory tract infection	2	0
Vaccination site abscess	2	0
Vaccination site infection	5	0
Vaccine breakthrough infection	1	0
Vestibulitis	1	0
Wound infection	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	2	0
<i>Infectious transmissions</i>		
Secondary transmission	2	0
<i>Influenza viral infections</i>		
Influenza	616	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	1	0
Bronchitis	6	0
Lower respiratory tract infection	84	1
Pleural infection	1	0
Pneumonia	20	2
Pneumonia aspiration	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	1	0
Orchitis	3	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Orthopox viral infections</i>		
Vaccinia virus infection	1	0
<i>Parvoviral infections</i>		
Erythema infectiosum	1	0
<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>		
Intestinal sepsis	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Sepsis	7	0
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Blister infected	1	0
Eczema infected	1	0
Impetigo	6	0
Infected skin ulcer	1	0
Pustule	11	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	15	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	11	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	1	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea capitis	1	0
Tinea infection	1	0
<i>Tuberculous infections</i>		
Lymph node tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	2	0
Chronic sinusitis	1	0
Laryngitis	7	0
Nasopharyngitis	327	0
Peritonsillar abscess	1	0
Pharyngitis	6	0
Rhinitis	8	0
Sinusitis	37	0
Tonsillitis	15	0
Upper respiratory tract infection	3	0
<i>Urinary tract infections</i>		
Cystitis	12	0
Kidney infection	6	0
Urinary tract infection	43	0
<i>Vascular infections</i>		
Lymphangitis	3	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Gastroenteritis viral	3	0
Meningitis viral	2	0
Pneumonia viral	2	0
Post viral fatigue syndrome	8	0
Sweating fever	62	0
Vestibular neuronitis	4	0
Viral infection	9	0
Viral labyrinthitis	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Viral myocarditis	1	0
Viral pharyngitis	6	0
Viral rash	7	0
Infections SOC TOTAL	2482	5

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Palate injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	2	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	3	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	8	0
Subdural haematoma	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	3	0
<i>Conditions caused by cold</i>		
Chillblains	18	0
<i>Cranial nerve injuries</i>		
Cranial nerve injury	1	0
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	25	0
Foetal exposure during pregnancy	11	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	590	0
Maternal exposure during pregnancy	273	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>		
Blindness traumatic	1	0
Eye contusion	2	0
Eye injury	7	0
<i>Fractures and dislocations NEC</i>		
Compression fracture	1	0
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	9	0
Heat stroke	9	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	8	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	2	0
Medication error	37	0
Wrong schedule	1	0
Wrong technique in device usage process	2	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Wrong technique in product usage process	1	0
Muscle, tendon and ligament injuries		
Epicondylitis	3	0
Ligament sprain	2	0
Muscle injury	5	0
Muscle rupture	1	0
Muscle strain	5	0
Tendon injury	2	0
Tendon rupture	1	0
Nerve injuries NEC		
Nerve injury	22	0
Nerve root injury lumbar	1	0
Neurological and psychiatric procedural complications		
Procedural dizziness	5	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod bite	5	0
Bite	1	0
Electric shock	6	0
Fall	56	0
Inflammation of wound	2	0
Injury	4	0
Multiple injuries	1	0
Nervous system injury	1	0
Stab wound	1	0
Struck by lightning	1	0
Wound complication	7	0
Wound haemorrhage	2	0
Non-site specific procedural complications		
Incision site pain	1	0
Infusion related reaction	1	0
Injection related reaction	36	0
Post procedural complication	1	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	28	0
Overdoses NEC		
Overdose	6	0
Peripheral nerve injuries		
Sciatic nerve injury	1	0
Ulnar nerve injury	1	0
Poisoning and toxicity		
Systemic toxicity	1	0
Toxicity to various agents	1	0
Product administration errors and issues		
Accidental overdose	72	0
Accidental underdose	1	0
Expired product administered	51	0
Extra dose administered	50	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Inappropriate schedule of product administration	79	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	10	0
Incorrect product administration duration	1	0
Incorrect route of product administration	2	0
Poor quality product administered	2	0
Product administered at inappropriate site	6	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	2	0
Product confusion errors and issues		
Product label confusion	4	0
Product dispensing errors and issues		
Product dispensing error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	1	0
Product transcribing errors and communication issues		
Product communication issue	1	0
Radiation injuries		
Sunburn	15	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Site specific injuries NEC		
Back injury	2	0
Head injury	10	0
Limb injury	54	0
Nasal injury	1	0
Skin injuries NEC		
Contusion	346	0
Scar	12	0
Scratch	2	0
Skin abrasion	1	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
Skull fractures, facial bone fractures and dislocations		
Jaw fracture	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Stoma complications		
Stoma site discomfort	1	0
Stoma site oedema	1	0
Thermal burns		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	13	0
Thermal burns of eye	6	0
Thoracic cage fractures and dislocations		
Sternal fracture	1	0
Vaccination related complications		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Vaccination complication	2	0
Injuries SOC TOTAL	2015	0

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Reaction Name	Total	Fatal
Investigations		
Adrenal medulla tests		
Norepinephrine increased	2	0
Auditory and vestibular diagnostic procedures		
Audiogram abnormal	1	0
Autoimmunity analyses		
Rheumatoid factor increased	1	0
Bacteria identification and serology (excl mycobacteria)		
Campylobacter test positive	1	0
Blood counts NEC		
Full blood count abnormal	1	0
Blood gas and acid base analyses		
Blood lactic acid	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	2	0
Oxygen saturation decreased	19	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	1	0
Blood glucose abnormal	1	0
Blood glucose decreased	2	0
Blood glucose increased	7	0
Cardiac auscultatory investigations		
Cardiac murmur	4	0
Heart sounds	5	0
Cardiac function diagnostic procedures		
Ejection fraction decreased	1	0
Central nervous system imaging procedures		
Computerised tomogram head	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Cholesterol analyses		
Blood cholesterol increased	2	0
Low density lipoprotein increased	1	0
Coagulation and bleeding analyses		
Bleeding time	1	0
Bleeding time abnormal	1	0
Blood fibrinogen	1	0
Blood thrombin	1	0
Coagulation time shortened	1	0
Fibrin D dimer increased	5	0
International normalised ratio decreased	1	0
International normalised ratio increased	2	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	1	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	3	0
Electrocardiogram change	1	0
Endocrine analyses and imaging NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Hormone level abnormal	16	0
Fertility analyses		
Semen analysis abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
Fungus identification and serology		
Fungal test	1	0
Gastrointestinal and abdominal imaging procedures		
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	1	0
Haematological analyses NEC		
Blood viscosity increased	1	0
Heart rate and pulse investigations		
Heart rate	273	0
Heart rate abnormal	22	0
Heart rate decreased	17	0
Heart rate increased	415	0
Heart rate irregular	88	0
Heart rate variability decreased	1	0
Maximum heart rate	1	0
Maximum heart rate increased	1	0
Pulse abnormal	2	0
Pulse absent	1	0
Sinus rhythm	3	0
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	6	0
Aspartate aminotransferase	2	0
Bile output	3	0
Blood bilirubin increased	1	0
Liver function test abnormal	8	0
Liver function test increased	1	0
Imaging procedures NEC		
X-ray	1	0
Immunology analyses NEC		
Immunology test	1	0
Immunology skin tests NEC		
Allergy alert test	1	0
Allergy alert test positive	1	0
Investigations NEC		
Blood test	1	0
Blood test abnormal	5	0
Blood test normal	2	0
Polymerase chain reaction positive	2	0
Mineral and electrolyte analyses		
Blood calcium increased	2	0
Blood iron	1	0
Blood iron decreased	3	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	2	0
Urine copper	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Bone scan	1	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Tender joint count	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	2	0
Electromyogram abnormal	1	0
Sensory level	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	2	0
Visual tracking test	1	0
Visual tracking test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	105	0
Body temperature abnormal	12	0
Body temperature decreased	18	0
Body temperature fluctuation	26	0
Body temperature increased	139	0
Breath sounds	1	0
Breath sounds abnormal	1	0
Grip strength	1	0
Grip strength decreased	3	0
Head lag	4	0
Lymph node palpable	5	0
Muscle strength abnormal	2	0
Ophthalmological examination	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	5	0
Respiratory rate decreased	6	0
Respiratory rate increased	10	0
Skin temperature	24	0
Temperature difference of extremities	6	0
Weight decreased	27	0
Weight increased	11	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	10	0
Platelet count normal	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	9	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Reproductive hormone analyses</i>		
Blood testosterone decreased	1	0
False negative pregnancy test	1	0
Pregnancy test	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Pregnancy test false positive	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	3	0
Pulmonary function test decreased	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	5	0
Therapeutic drug monitoring analyses		
Analgesic drug level	5	0
Thyroid analyses		
Tri-iodothyronine decreased	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	1	0
Blood lactate dehydrogenase increased	1	0
Urinalysis NEC		
Blood urine	5	0
Blood urine present	27	0
Protein urine	1	0
pH urine	1	0
Urinary tract function analyses NEC		
Urine output	12	0
Urine output decreased	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	2	0
Blood pressure decreased	11	0
Blood pressure diastolic increased	1	0
Blood pressure increased	38	0
Blood pressure measurement	10	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 antibody test positive	2	0
SARS-CoV-2 test	5	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	7	0
Vitamin analyses		
Blood folate decreased	1	0
White blood cell analyses		
Neutrophil count	1	0
Neutrophil count decreased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	2	0
Investigations SOC TOTAL	1594	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	3	0
Decreased appetite	447	0
Food craving	2	0
Food refusal	4	0
Hyperphagia	5	0
Hypophagia	3	0
Increased appetite	9	0
Salt craving	1	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	5	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	22	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	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	2	0
Food intolerance	2	0
Gluten sensitivity	1	0
Histamine intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	5	0
Abnormal weight gain	9	0
Feeding disorder	54	0
Food aversion	5	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
Poor feeding infant	1	0
Weight loss poor	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	7	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	10	0
<i>Iron excess</i>		
Haemochromatosis	1	0
<i>Potassium imbalance</i>		
Hypokalaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Dehydration	107	0
<i>Total fluid volume increased</i>		
Fluid retention	11	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	2	0
Metabolic disorders SOC TOTAL	741	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	61	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	8	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	2	0
<i>Bone disorders NEC</i>		
Bone erosion	1	0
Exostosis	2	0
Jaw cyst	1	0
Jaw disorder	2	0
Medial tibial stress syndrome	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	116	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	105	0
Pubic pain	1	0
Spinal pain	19	0
<i>Bursal disorders</i>		
Bursitis	24	0
<i>Cartilage disorders</i>		
Costochondritis	23	0
<i>Connective tissue disorders NEC</i>		
Morphoea	1	0
Polymyalgia rheumatica	6	0
Reynold's syndrome	2	0
<i>Extremity deformities</i>		
Finger deformity	1	0
Foot deformity	2	0
Hand deformity	2	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0
<i>Joint related disorders NEC</i>		
Greater trochanteric pain syndrome	1	0
Hypermobility syndrome	1	0
Joint lock	10	0
Periarthritis	56	0
Rotator cuff syndrome	6	0
Temporomandibular joint syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2636	0
Joint effusion	1	0
Joint noise	3	0
Joint range of motion decreased	1	0
Joint stiffness	79	0
Joint swelling	92	0
Joint vibration	2	0
Joint warmth	7	0
<i>Lupus erythematosus (incl subtypes)</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
Muscle infections and inflammations		
Myositis	10	0
Muscle pains		
Fibromyalgia	26	0
Myalgia	3419	0
Myalgia intercostal	1	0
Muscle related signs and symptoms NEC		
Muscle atrophy	2	0
Muscle discomfort	3	0
Muscle fatigue	116	0
Muscle haemorrhage	1	0
Muscle spasms	511	0
Muscle swelling	17	0
Muscle tightness	30	0
Muscle twitching	93	0
Myosclerosis	1	0
Muscle tone abnormalities		
Muscle rigidity	5	0
Nuchal rigidity	5	0
Trismus	11	0
Muscle weakness conditions		
Muscular weakness	258	0
Musculoskeletal and connective tissue conditions NEC		
Growth retardation	1	0
Limb mass	3	0
Mastication disorder	2	0
Mobility decreased	30	0
Muscle contracture	1	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	486	0
Weight bearing difficulty	1	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
Plantar fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	850	0
Flank pain	18	0
Limb discomfort	409	0
Musculoskeletal chest pain	68	0
Musculoskeletal discomfort	27	0
Musculoskeletal pain	25	0
Neck pain	503	0
Pain in extremity	4076	1
Sacral pain	1	0
Myopathies		
Rhabdomyolysis	1	0
Osteoarthropathies		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Osteoarthritis	6	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	3	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	21	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	59	0
Fluctuance	1	0
Groin pain	27	0
Neck mass	14	0
Soft tissue swelling	2	0
<i>Spine and neck deformities</i>		
Spinal stenosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	4	0
Arthritis reactive	19	0
Axial spondyloarthritis	1	0
Spondylitis	1	0
<i>Synovial disorders</i>		
Synovial cyst	5	0
Synovitis	2	0
<i>Tendon disorders</i>		
Tendon pain	4	0
Tendonitis	8	0
Trigger finger	3	0
<i>Trunk deformities</i>		
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	14493	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage II	1	0
B-cell lymphoma stage III	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	2	0
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	4	0
<i>Breast neoplasms unspecified malignancy</i>		
Phyllodes tumour	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	9	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>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal carcinoma	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Plasma cell neoplasms NEC</i>		
Hypergammaglobulinaemia benign monoclonal	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	2	0
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	4	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Keratoacanthoma	1	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	2	0
<i>Urinary tract neoplasms unspecified malignancy NEC</i>		
Renal neoplasm	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	2	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	1	0
Neoplasms SOC TOTAL	49	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	5	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	18	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	2	0
Orthostatic intolerance	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral artery embolism	1	0
Cerebral haemorrhage	4	2
Cerebral infarction	1	0
Cerebrovascular accident	41	1
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	0
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	5	0
Lacunar infarction	1	0
Ruptured cerebral aneurysm	1	1
Subarachnoid haemorrhage	6	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	2	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	4	0
Cerebral venous thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervical radiculopathy	1	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	5	0
Balance disorder	99	0
Coordination abnormal	7	0
Dysstasia	18	0
Nystagmus	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	9	0
Dysgraphia	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	3	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Consciousness fluctuating	1	0
Depressed level of consciousness	15	0
Lethargy	534	0
Loss of consciousness	282	0
Somnolence	287	0
Stupor	1	0
Syncope	1142	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	2	0
Bradykinesia	4	0
Clumsiness	4	0
Dyskinesia	16	0
Extrapyramidal disorder	2	0
Fine motor delay	1	0
Fine motor skill dysfunction	4	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	19	0
Motor dysfunction	3	0
Movement disorder	13	0
Psychomotor hyperactivity	5	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	103	0
Facial nerve disorder	1	0
Facial paralysis	58	0
Facial paresis	12	0
Facial spasm	7	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	8	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	66	0
Cold-stimulus headache	11	0
Drug withdrawal headache	2	0
Headache	8498	0
Medication overuse headache	1	0
New daily persistent headache	2	0
Occipital neuralgia	1	0
Primary cough headache	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	107	0
Tension headache	171	0
Thunderclap headache	3	0
Vascular headache	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	3	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	13	0
<i>Memory loss (excl dementia)</i>		
Amnesia	61	0
Memory impairment	39	0
Transient global amnesia	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	26	0
Disturbance in attention	90	0
Mental impairment	15	0
<i>Migraine headaches</i>		
Basilar migraine	1	0
Hemiplegic migraine	7	0
Migraine	855	0
Migraine with aura	50	0
Migraine without aura	3	0
Retinal migraine	5	0
Typical aura without headache	1	0
Vestibular migraine	4	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	6	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	4	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	5	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	6	0
Progressive multiple sclerosis	1	0
Uhthoff's phenomenon	1	0
<i>Muscle tone abnormal</i>		
Drop attacks	1	0
Hypotonia	10	0
Stiff leg syndrome	3	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	7	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	31	0
Narcolepsy	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	5	0
Psychomotor skills impaired	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Tunnel vision	13	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Clonus	2	0
Dizziness	3391	0
Dizziness exertional	14	0
Dizziness postural	228	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	70	0
Meningism	1	0
Neurological symptom	12	0
Persistent postural-perceptual dizziness	3	0
Presyncope	262	0
Tongue biting	2	0
Unresponsive to stimuli	13	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	2	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
<i>Neuromuscular junction dysfunction</i>		
Myasthenia gravis	1	0
<i>Olfactory nerve disorders</i>		
Anosmia	39	0
Hyposmia	2	0
Parosmia	47	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	5	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	6	0
Burning sensation	134	0
Dysaesthesia	1	0
Formication	8	0
Hemianaesthesia	1	0
Hemihypoaesthesia	1	0
Hyperaesthesia	56	0
Hypoaesthesia	688	0
Paraesthesia	984	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	6	0
Hemiparesis	5	0
Hemiplegia	12	0
Monoparesis	24	0
Monoplegia	29	0
Paralysis	35	0
Paraparesis	2	0
Paresis	2	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	12	0
Reduced facial expression	1	0
<i>Partial complex seizures</i>		
Focal dyscognitive seizures	2	0
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Neuralgic amyotrophy	4	0
Neuritis	3	0
Neuropathy peripheral	14	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	2	0
Seizures and seizure disorders NEC		
Atonic seizures	1	0
Epilepsy	24	0
Febrile convulsion	6	0
Myoclonic epilepsy	1	0
Partial seizures	7	0
Psychogenic seizure	1	0
Seizure	202	0
Seizure anoxic	2	0
Seizure cluster	1	0
Status epilepticus	28	0
Tonic clonic movements	3	0
Tonic convulsion	5	0
Sensory abnormalities NEC		
Ageusia	93	0
Allodynia	3	0
Aura	3	0
Complex regional pain syndrome	1	0
Dysgeusia	232	0
Electric shock sensation	14	0
Hypogeusia	1	0
Neuralgia	151	0
Post herpetic neuralgia	3	0
Restless legs syndrome	48	0
Sensory disturbance	28	0
Sensory loss	34	0
Taste disorder	53	0
Vibratory sense increased	2	0
Sleep disturbances NEC		
Sleep deficit	6	0
Speech and language abnormalities		
Dysarthria	42	0
Incoherent	12	0
Slow speech	5	0
Speech disorder	18	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	3	0
Radiculopathy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	22	0
Tremor (excl congenital)		
Essential tremor	2	0
Head titubation	2	0
Tremor	721	0
Trigeminal disorders		
Trigeminal neuralgia	8	0
Trigeminal neuritis	1	0
Nervous system disorders SOC TOTAL	20866	4

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	69	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	4	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
Subchorionic haemorrhage	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	5	0
<i>Maternal complications of labour NEC</i>		
Uterine atony	1	0
Uterine hypertonus	3	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
Uterine irritability	1	0
<i>Multiple pregnancies</i>		
Twin pregnancy	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
Term birth	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Stillbirth	1	1
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	108	1

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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>		
Oversensing	1	0
Thrombosis in device	2	0
Undersensing	2	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 label issues</i>		
Product label issue	3	0
<i>Product physical issues</i>		
Product after taste	1	0
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
<i>Product supply and availability issues</i>		
Product availability issue	2	0
null SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	6	0
Breath holding	4	0
Staring	1	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	3	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	25	0
Anxiety	264	0
Nervousness	49	0
Stress	22	0
Tension	10	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	5	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Disinhibition	1	0
Homicidal ideation	1	0
Impatience	1	0
Paranoia	7	0
Personality change	3	0
Social avoidant behaviour	1	0
Violence-related symptom	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	62	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	233	0
Disorientation	96	0
<i>Deliria</i>		
Delirium	59	1
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	3	0
Delusion of parasitosis	1	0
<i>Depressive disorders</i>		
Depression	98	0
Depression suicidal	4	0
Major depression	3	0
Mixed anxiety and depressive disorder	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	3	0
Dissociation	13	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	7	0
Insomnia	511	0
Middle insomnia	14	0
Terminal insomnia	13	0
<i>Dyssomnias</i>		
Poor quality sleep	101	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	14	0
Emotional disorder	21	0
Emotional distress	12	0
Emotional poverty	1	0
Euphoric mood	12	0
Frustration tolerance decreased	4	0
Irritability	54	0
Mood altered	20	0
<i>Factitious disorders</i>		
Factitious disorder	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	7	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
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	18	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	134	0
Hallucination, auditory	6	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	5	0
Hallucinations, mixed	3	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	62	0
<i>Mental disorders NEC</i>		
Mental disorder	4	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	1	0
Depressed mood	98	0
Feeling of despair	5	0
Negative thoughts	2	0
Sense of a foreshortened future	1	0
Tearfulness	7	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Mood alterations with manic symptoms</i>		
Mania	5	0
<i>Mood disorders NEC</i>		
Affective disorder	2	0
Apathy	13	0
Listless	11	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Dermatophagia	3	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	57	0
Panic reaction	12	0
<i>Paraphilias and paraphilic disorders</i>		
Exhibitionism	1	0
<i>Parasomnias</i>		
Abnormal dreams	40	0
Abnormal sleep-related event	1	0
Nightmare	66	0
Sleep inertia	1	0
Sleep talking	3	0
Sleep terror	5	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	3	0
Deja vu	1	0
Derealisation	3	0
Illusion	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	14	0
<i>Psychiatric symptoms NEC</i>		
Helplessness	1	0
Hypervigilance	2	0
Psychiatric symptom	6	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	2	0
<i>Sexual arousal disorders</i>		
Disturbance in sexual arousal	1	0
<i>Sexual desire disorders</i>		
Libido decreased	6	0
Libido increased	1	0
Loss of libido	6	0
<i>Sleep disorders NEC</i>		
Sleep disorder	79	0
<i>Somatic symptom disorders</i>		
Conversion disorder	5	0
Habit cough	7	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	4	0
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	4	0
Head banging	6	0
<i>Stress disorders</i>		
Acute stress disorder	1	0
Post-traumatic stress disorder	1	0
<i>Substance related and addictive disorders</i>		
Alcoholism	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	2	0
Suicidal behaviour	2	0
Suicidal ideation	20	0
Suicide attempt	3	0
<i>Thinking disturbances</i>		
Bradyphrenia	4	0
Intrusive thoughts	1	0
Tachyphrenia	5	0
Thinking abnormal	5	0
Thought blocking	2	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	2580	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	2	0
Bladder pain	10	0
Dysuria	10	0
Incontinence	17	0
Micturition urgency	16	0
Pollakiuria	45	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	19	0
Urinary retention	9	0
Urinary straining	2	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	4	0
Urinary bladder haemorrhage	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	1	0
<i>Genitourinary tract infections and inflammations NEC</i>		
Urinary tract inflammation	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis acute	1	0
IgA nephropathy	2	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	3	0
Loss of bladder sensation	2	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal disorders NEC</i>		
Renal disorder	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	6	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	2	0
Renal impairment	2	0
Renal injury	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vein thrombosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	22	0
Haematuria	9	0
Loin pain haematuria syndrome	1	0
Urine abnormality	5	0
Urine odour abnormal	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	8	0
Nocturia	1	0
Polyuria	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal pain	113	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	335	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	6	0
<i>Breast disorders NEC</i>		
Breast enlargement	4	0
Breast mass	20	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	4	0
<i>Breast signs and symptoms</i>		
Breast discharge	3	0
Breast discomfort	2	0
Breast haemorrhage	1	0
Breast oedema	1	0
Breast pain	156	0
Breast swelling	23	0
Breast tenderness	16	0
Nipple pain	2	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Cervix haemorrhage uterine	1	0
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	3	0
Erectile dysfunction	15	0
Erection increased	1	0
Nocturnal emission	1	0
Organic erectile dysfunction	9	0
Painful ejaculation	1	0
Priapism	1	0
Spontaneous penile erection	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	2	0
Lactation disorder	3	0
Lactation puerperal increased	2	0
Suppressed lactation	10	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	10	0
Premature menopause	5	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	23	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	486	0
Intermenstrual bleeding	255	0
Menstrual discomfort	4	0
Menstrual disorder	419	0
Menstruation irregular	692	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Premenstrual pain	23	0
Premenstrual syndrome	18	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	103	0
Hypomenorrhoea	117	0
Menstruation delayed	849	0
Oligomenorrhoea	35	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1074	0
Menometrorrhagia	9	0
Polymenorrhoea	180	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	7	0
Polycystic ovaries	10	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovulation pain	21	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	22	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 blister	1	0
Genital haemorrhage	3	0
Genital paraesthesia	1	0
Genital ulceration	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital odour	1	0
Genital pain	3	0
Genital rash	1	0
Pelvic discomfort	1	0
Pelvic pain	36	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	8	0
Scrotal swelling	1	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	5	0
Infertility female	1	0
Sexual dysfunction	2	0
<i>Spermatogenesis and semen disorders</i>		
Haematospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0
Testicular mass	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Testicular pain	21	0
Testicular swelling	7	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	22	0
Metrorrhoea	1	0
Uterine haemorrhage	12	0
Uterine pain	8	0
<i>Uterine neoplasms</i>		
Uterine polyp	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	17	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	348	0
Vaginal ulceration	3	0
Vulval haemorrhage	10	0
Vulval ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	21	0
Vaginal odour	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	5240	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	1672	0
Dyspnoea at rest	1	0
Dyspnoea exertional	7	0
Hyperventilation	16	0
Hypopnoea	32	0
Hypoventilation	1	0
Irregular breathing	6	0
Mouth breathing	1	0
Obstructive sleep apnoea syndrome	2	0
Respiration abnormal	23	0
Respiratory arrest	2	1
Respiratory distress	2	0
Sleep apnoea syndrome	4	0
Tachypnoea	7	0
<i>Bronchospasm and obstruction</i>		
Asthma	81	0
Asthma exercise induced	2	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	2	0
Childhood asthma	2	0
Chronic obstructive pulmonary disease	1	0
Obstructive airways disorder	1	0
Wheezing	136	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	3	0
Cough	650	0
Haemoptysis	5	0
Productive cough	39	0
Sputum discoloured	6	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	2	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	1	0
Pneumonitis	5	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	16	0
Lower respiratory tract congestion	2	0
Pleuritic pain	2	0
Pulmonary haemorrhage	1	0
Pulmonary pain	29	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	72	0
Nasal inflammation	1	0
Rhinitis allergic	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Nasal disorders NEC</i>		
Epistaxis	203	0
Nasal crusting	1	0
Nasal dryness	3	0
Nasal oedema	2	0
Nasal pruritus	3	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	5	0
Sinus congestion	13	0
Sinus disorder	4	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	2	0
Pharyngeal hypoaesthesia	5	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	66	0
Tonsillar erythema	3	0
Tonsillar hypertrophy	17	0
Tonsillar inflammation	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	11	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	4	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	5	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	74	2
Pulmonary thrombosis	3	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	2	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	4	0
Painful respiration	4	0
Respiratory symptom	4	0
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	2	0
Lung disorder	1	0
Pulmonary mass	1	0
Respiratory disorder	2	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	22	0
Catarrh	7	0
Choking	7	0
Dry throat	31	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Dysphonia	25	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	9	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	4	0
Oropharyngeal pain	600	0
Paranasal sinus discomfort	8	0
Rhinalgia	6	0
Rhinorrhoea	178	0
Sinus pain	76	0
Sneezing	61	0
Throat irritation	44	0
Throat tightness	56	0
Upper-airway cough syndrome	5	0
Yawning	9	0
Respiratory disorders SOC TOTAL	4459	3

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 20-May-2022

Data Lock Date: 18-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	38	0
Acne cystic	2	0
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	74	0
Alopecia areata	17	0
Alopecia totalis	2	0
<i>Angioedemas</i>		
Angioedema	67	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	291	0
Hidradenitis	2	0
Hyperhidrosis	1016	0
Miliaria	71	0
Night sweats	318	0
<i>Bullous conditions</i>		
Blister	102	0
Blister rupture	2	0
Blood blister	3	0
Dermatitis bullous	5	0
Erythema multiforme	15	0
Pemphigoid	2	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	107	0
Pain of skin	149	0
Papule	22	0
Scab	5	0
Scar pain	6	0
Sensitive skin	149	0
Skin burning sensation	78	0
Skin discolouration	44	0
Skin discomfort	2	0
Skin disorder	2	0
Skin induration	8	0
Skin lesion	26	0
Skin necrosis	2	0
Skin odour abnormal	3	0
Skin plaque	1	0
Skin reaction	124	0
Skin sensitisation	16	0
Skin swelling	30	0
Skin texture abnormal	1	0
Skin tightness	7	0
Skin warm	238	0
Skin weeping	2	0
Yellow skin	5	0

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Skin disorders Skin disorders cont'd		
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	50	0
Dermatitis allergic	117	0
Dermatitis atopic	19	0
Dermatitis contact	10	0
Dyshidrotic eczema	12	0
Eczema	90	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	2	0
Flagellate dermatitis	1	0
Hand dermatitis	1	0
Neurodermatitis	1	0
Skin irritation	39	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	4	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	1228	0
Vancomycin infusion reaction	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	2	1
Exfoliative rash	4	0
Skin exfoliation	23	0
<i>Hyperpigmentation disorders</i>		
Ephelides	2	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Skin hypopigmentation	2	0
Vitiligo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
Nail ridging	1	0
Onychalgia	1	0
Onychoclasia	2	0
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	11	0
<i>Papulosquamous conditions</i>		
Lichen planus	5	0
Parapsoriasis	1	0
Pityriasis rosea	19	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	20	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	2	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	2	0
Hair texture abnormal	1	0
Piloerection	17	0

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Skin disorders Skin disorders cont'd		
Trichodynia	1	0
Trichorrhexis	1	0
Pruritus NEC		
Itching scar	4	0
Pruritus	2584	0
Psoriatic conditions		
Guttate psoriasis	2	0
Palmoplantar pustulosis	1	0
Psoriasis	37	0
Rebound psoriasis	1	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Petechiae	24	0
Purpura	12	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	2964	0
Rash erythematous	1121	0
Rash macular	205	0
Rash maculo-papular	7	0
Rash morbilliform	9	0
Rash papular	187	0
Rash pruritic	634	0
Rash vesicular	14	0
Rosaceas		
Rosacea	2	0
Scaly conditions		
Pityriasis	6	0
Sebaceous gland disorders		
Seborrhoea	2	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	4	0
Skin mass	13	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	8	0
Skin ulcer	6	0
Skin cysts and polyps		
Dermal cyst	8	0
Skin dystrophies		
Keloid scar	2	0
Skin wrinkling	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	4	0
Skin hypoplasias and atrophies		
Skin atrophy	3	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	1	0
Needle track marks	2	0
Skin vasculitides		
Capillaritis	1	0
Cutaneous vasculitis	3	0
Vasculitic rash	2	0

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Skin disorders Skin disorders cont'd		
<i>Skin vasomotor conditions</i>		
Livedo reticularis	5	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	5	0
Cold urticaria	1	0
Idiopathic urticaria	5	0
Mechanical urticaria	26	0
Urticaria	716	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	8	0
Urticaria contact	1	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	13413	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	2	0
Menopause	9	0
Postmenopause	2	0
<i>Disability issues</i>		
Bedridden	10	0
Disability	1	0
Immobile	5	0
Impaired driving ability	2	0
Impaired work ability	3	0
Loss of personal independence in daily activities	13	0
Sight disability	2	0
<i>Employment issues</i>		
Retirement	2	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	6	0
<i>Social issues NEC</i>		
Social problem	1	0
Tattoo	1	0
Social circumstances SOC TOTAL	61	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Light anaesthesia	1	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	2	0
<i>Contraceptive methods female</i>		
Post coital contraception	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Eye therapeutic procedures NEC</i>		
Eye irrigation	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	3	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	22	0
Immunisation	21	0
Influenza immunisation	1	0
Vaccine coadministration	1	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	3	0
<i>Therapeutic procedures NEC</i>		
Bed rest	4	0
Botulinum toxin injection	1	0
Hospitalisation	3	0
Injection	17	0
Interchange of vaccine products	35	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	129	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm ruptured	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	4	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	3	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	9	0
Neurogenic shock	1	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Bloody discharge	2	0
Haematoma	8	0
Haemorrhage	241	0
Internal haemorrhage	3	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	29	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	3	0
Embolism venous	1	0
Thrombosis	70	0
Venous thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Ischaemia	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	8	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	7	0
Deep vein thrombosis	62	0
Pelvic venous thrombosis	2	0
Superficial vein thrombosis	3	0
Thrombophlebitis	6	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	14	0
Erythromelalgia	1	0
Flushing	59	0
Hot flush	319	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	1	0
Peripheral coldness	110	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	11	0
<i>Phlebitis NEC</i>		
Phlebitis	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	90	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	8	0
Varicose vein ruptured	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	123	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	2	0
Hypotension	113	0
Orthostatic hypotension	6	0
<i>Vasculitides NEC</i>		
Vasculitis	7	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1359	0
TOTAL REACTIONS FOR DRUG	128525	56
TOTAL REPORTS	38756	
TOTAL FATAL OUTCOME REPORTS		56