

## COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 14-Jan-2022  
Data Lock Date: 12-Jan-2022 18:30:17

All UK spontaneous reports received up to and including 12/01/2022 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.

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Iron deficiency anaemia	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	5	0
<i><b>Anaemias haemolytic NEC</b></i>		
Haemolytic anaemia	1	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	6	0
Spontaneous haematoma	1	0
<i><b>Coagulopathies</b></i>		
Antiphospholipid syndrome	1	0
Coagulopathy	3	0
Hypercoagulation	1	0
<i><b>Eosinophilic disorders</b></i>		
Eosinophilia	1	0
<i><b>Haematological disorders</b></i>		
Blood disorder	1	0
Mast cell activation syndrome	1	0
Mastocytosis	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	320	0
Lymph node ulcer	1	0
Lymphadenitis	24	0
Lymphadenopathy	1907	0
<i><b>Neutropenias</b></i>		
Autoimmune neutropenia	1	0
Neutropenia	2	0
<i><b>Polycythaemia (excl rubra vera)</b></i>		
Stress polycythaemia	1	0
<i><b>Sickle cell trait and disorders</b></i>		
Sickle cell anaemia with crisis	1	0
<i><b>Spleen disorders</b></i>		
Splenic infarction	1	0
Splenic vein thrombosis	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	7	0
Thrombocytopenia	26	0
Thrombocytopenic purpura	2	0
<b>Blood disorders SOC TOTAL</b>	<b>2317</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	3	0
Bundle branch block left	1	0
Bundle branch block right	2	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	13	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	3	0
Palpitations	1379	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	1	0
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery occlusion	1	0
Coronary artery stenosis	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	3	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	2	0
Angina pectoris	54	0
Myocardial infarction	20	0
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	1	0
<i><b>Mitral valvular disorders</b></i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	4	0
Left ventricular dysfunction	3	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
Myocardial oedema	1	0
<i><b>Noninfectious myocarditis</b></i>		
Hypersensitivity myocarditis	1	0
Myocarditis	180	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	95	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial effusion	2	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	25	0
Bradycardia	13	0
Cardiac fibrillation	1	0
Cardiac flutter	118	0
Extrasystoles	38	0
Paroxysmal arrhythmia	1	0
Tachyarrhythmia	2	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Tachycardia	589	0
Tachycardia foetal	1	0
<b><i>Supraventricular arrhythmias</i></b>		
Atrial fibrillation	28	0
Atrial flutter	9	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	9	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	6	0
<b><i>Ventricular arrhythmias and cardiac arrest</i></b>		
Cardiac arrest	12	3
Ventricular extrasystoles	3	0
Ventricular tachycardia	4	0
<b>Cardiac disorders SOC TOTAL</b>	<b>2642</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	2	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Limb malformation	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear canal erythema	1	0
Ear congestion	7	0
Ear discomfort	7	0
Ear disorder	4	0
Ear inflammation	1	0
Ear pain	273	0
Ear swelling	5	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube obstruction	1	0
<i><b>External ear disorders NEC</b></i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i><b>External ear infections and inflammations</b></i>		
External ear inflammation	1	0
<i><b>Hearing losses</b></i>		
Deafness	43	0
Deafness transitory	1	0
Deafness unilateral	7	0
Hypoacusis	35	0
Sudden hearing loss	11	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	7	0
<i><b>Inner ear disorders NEC</b></i>		
Meniere's disease	1	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	3	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	18	0
Tinnitus	352	0
Vertigo	260	0
Vertigo labyrinthine	2	0
Vertigo positional	12	0
<i><b>Middle ear infections and inflammations</b></i>		
Middle ear inflammation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>1057</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	1	0
Thyroiditis subacute	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	7	0
Ovulation delayed	11	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	6	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	3	0
<b>Endocrine disorders SOC TOTAL</b>	<b>40</b>	<b>0</b>

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<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	3	0
<i><b>Cataract conditions</b></i>		
Cataract	1	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Chorioretinopathy	2	0
Vitreous detachment	1	0
Vitreous floaters	14	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	1	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	8	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	31	0
Eyelid ptosis	3	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iridocyclitis	1	0
Iritis	2	0
Uveitis	9	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	33	0
Lacrimation increased	13	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	2	0
Eyelid cyst	1	0
Eyelid irritation	1	0
Eyelid oedema	1	0
Eyelid rash	2	0
Swelling of eyelid	27	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Lagophthalmos	1	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haematoma	1	0
Eye haemorrhage	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	3	0
Eye oedema	1	0
Eye pain	303	0
Eye swelling	116	0
Eyelid disorder	1	0
Eyelids pruritus	1	0
Ocular discomfort	11	0
Periorbital oedema	3	0
Periorbital swelling	19	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	3	0
Eye discharge	2	0
Eye inflammation	6	0
Eye irritation	16	0
Eye pruritus	35	0
Ocular hyperaemia	40	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Extraocular muscle paresis	1	0



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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Eye movement disorder	7	0
Gaze palsy	1	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	2	0
Asthenopia	24	0
Foreign body sensation in eyes	7	0
Hypoaesthesia eye	6	0
Photophobia	125	0
<b>Optic disc abnormalities NEC</b>		
Optic discs blurred	1	0
Papilloedema	1	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic ischaemic neuropathy	1	0
<b>Orbital infections, inflammations and irritations</b>		
Orbital myositis	1	0
<b>Orbital structural change, deposit and degeneration</b>		
Lid sulcus deepened	2	0
<b>Pupil disorders</b>		
Mydriasis	3	0
<b>Refractive and accommodative disorders</b>		
Accommodation disorder	1	0
Astigmatism	3	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	7	0
<b>Retinopathies NEC</b>		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
<b>Scleral infections, irritations and inflammations</b>		
Episcleritis	5	0
<b>Scleral structural change, deposit and degeneration</b>		
Scleral disorder	1	0
<b>Structural change, deposit and degeneration of eye NEC</b>		
Exophthalmos	1	0
<b>Visual colour distortions</b>		
Cyanopsia	1	0
Xanthopsia	2	0
<b>Visual disorders NEC</b>		
Diplopia	27	0
Halo vision	4	0
Metamorphopsia	5	0
Photopsia	28	0
Scintillating scotoma	1	0
Vision blurred	271	0
<b>Visual field disorders</b>		
Visual field defect	4	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Blindness	25	0
Blindness transient	5	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	50	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
<b>Eye disorders SOC TOTAL</b>	<b>1350</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	2	0
<i>Anal and rectal pains</i>		
Proctalgia	7	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	4	0
Colitis ulcerative	7	0
Crohn's disease	7	0
Inflammatory bowel disease	3	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 paraesthesia	5	0
Hyperaesthesia teeth	6	0
Toothache	32	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1056	0
Diarrhoea haemorrhagic	5	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	133	0
Epigastric discomfort	3	0
Eructation	16	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	10	0
Faeces soft	1	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	66	0
Flatulence	39	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	6	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	301	0
Abdominal pain lower	23	0
Abdominal pain upper	784	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal rigidity	3	0
Abdominal tenderness	3	0
Gastrointestinal pain	33	0
Oesophageal pain	1	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	39	0
Gastric dilatation	2	0
Gastrooesophageal reflux disease	34	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Food poisoning	1	0
Functional gastrointestinal disorder	2	0
Gastric disorder	1	0
Gastrointestinal disorder	3	0
Lymphoid hyperplasia of intestine	1	0
Stomach mass	1	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	1	0
Change of bowel habit	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Gastrointestinal inflammation	1	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Hyperchlorhydria	2	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	143	0
Acute abdomen	1	0
Anal incontinence	3	0
Breath odour	8	0
Dysphagia	30	0
Odynophagia	7	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	1	0
Frequent bowel movements	6	0
Irritable bowel syndrome	14	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	1	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	2	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	1	0
Mesenteric vein thrombosis	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	19	0
Gingival swelling	7	0
Noninfective gingivitis	2	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	13	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoids	5	0
<b><i>Intestinal haemorrhages</i></b>		

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Anal haemorrhage	1	0
Rectal haemorrhage	15	0
<b>Malabsorption syndromes</b>		
Coeliac disease	1	0
<b>Nausea and vomiting symptoms</b>		
Discoloured vomit	1	0
Nausea	4328	0
Regurgitation	1	0
Retching	29	0
Vomiting	1635	0
Vomiting projectile	17	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	3	0
Haematemesis	7	0
Haematochezia	9	0
Melaena	1	0
Upper gastrointestinal haemorrhage	5	0
<b>Oesophagitis (excl infective)</b>		
Oesophagitis	1	0
<b>Oral dryness and saliva altered</b>		
Aptyalism	1	0
Dry mouth	97	0
Lip dry	9	0
Saliva altered	2	0
Salivary hypersecretion	12	0
<b>Oral soft tissue disorders NEC</b>		
Chapped lips	2	0
Cheilitis	3	0
Enlarged uvula	1	0
Lip blister	3	0
Lip disorder	1	0
Oral disorder	1	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	4	0
Oral blood blister	4	0
<b>Oral soft tissue signs and symptoms</b>		
Coating in mouth	2	0
Hypoaesthesia oral	80	0
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	11	0
Lip pruritus	3	0
Oral discomfort	10	0
Oral mucosal blistering	1	0
Oral mucosal eruption	2	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	29	0
Oral pruritus	2	0
Paraesthesia oral	119	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	1	0
Lip swelling	190	0

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Mouth swelling	22	0
<b>Peptic ulcers and perforation</b>		
Peptic ulcer haemorrhage	3	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Rectal inflammations NEC</b>		
Proctitis	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland mass	1	0
Salivary gland pain	3	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	3	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	4	0
Lip ulceration	4	0
Mouth ulceration	92	0
Stomatitis	4	0
<b>Tongue disorders</b>		
Glossitis	6	0
Tongue disorder	9	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
<b>Tongue signs and symptoms</b>		
Glossodynia	30	0
Stiff tongue	1	0
Swollen tongue	88	0
Tongue blistering	2	0
Tongue coated	5	0
Tongue discolouration	3	0
Tongue discomfort	5	0
Tongue dry	3	0
Tongue eruption	1	0
Tongue movement disturbance	1	0
Tongue oedema	3	0
Tongue pruritus	1	0
Tongue spasm	1	0
<b>Tooth missing</b>		
Tooth loss	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>9886</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	1	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
<b><i>Adverse effect absent</i></b>		
No adverse event	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	10	0
Application site inflammation	1	0
Application site joint erythema	1	0
Application site pain	2	0
Application site pruritus	10	0
Application site rash	1	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	4	0
<b><i>Asthenic conditions</i></b>		
Asthenia	528	0
Chronic fatigue syndrome	6	0
Decreased activity	1	0
Fatigue	5908	0
Malaise	1017	1
Sluggishness	2	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	2	0
Hypothermia	5	0
Temperature regulation disorder	3	0
<b><i>Complications associated with device NEC</i></b>		
Injury associated with device	1	0
<b><i>Death and sudden death</i></b>		
Death	14	14
Sudden death	3	3
<b><i>Febrile disorders</i></b>		
Pyrexia	6320	1
<b><i>Feelings and sensations NEC</i></b>		
Chills	3813	0
Feeling abnormal	424	0
Feeling cold	357	0
Feeling drunk	16	0
Feeling hot	344	0
Feeling jittery	11	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Feeling of body temperature change	119	0
Hangover	20	0
Hunger	17	0
Sensation of blood flow	1	0
Sensation of foreign body	7	0
Temperature intolerance	22	0
Thirst	114	0
Thirst decreased	1	0
<b>Gait disturbances</b>		
Gait disturbance	28	0
Gait inability	15	0
Loss of control of legs	3	0
<b>General signs and symptoms NEC</b>		
Condition aggravated	29	0
Crepitations	1	0
Crying	33	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	6	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	612	0
Induration	10	0
Influenza like illness	749	0
Irritability postvaccinal	1	0
Local reaction	26	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2102	0
Screaming	6	0
Secretion discharge	2	0
Swelling	1173	0
Swelling face	187	0
<b>Implant and catheter site reactions</b>		
Catheter site related reaction	1	0
Implant site warmth	3	0
<b>Inflamations</b>		
Granuloma	1	0
Inflammation	177	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
<b>Infusion site reactions</b>		
Infusion site erythema	3	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
<b>Injection site reactions</b>		



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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injected limb mobility decreased	7	0
Injection site bruising	14	0
Injection site cyst	1	0
Injection site discolouration	1	0
Injection site erythema	205	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	15	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	1	0
Injection site mass	207	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site oedema	5	0
Injection site pain	810	0
Injection site paraesthesia	2	0
Injection site plaque	1	0
Injection site pruritus	129	0
Injection site rash	206	0
Injection site reaction	22	0
Injection site swelling	105	0
Injection site urticaria	56	0
Injection site vesicles	3	0
Injection site warmth	102	0
<b>Interactions</b>		
Alcohol interaction	1	0
Drug interaction	2	0
<b>Mass conditions NEC</b>		
Cyst	8	0
Mass	29	0
Nodule	6	0
<b>Mucosal findings abnormal</b>		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema mucosal	1	0
<b>Necrosis NEC</b>		
Necrosis	1	0
<b>Oedema NEC</b>		
Face oedema	8	0
Localised oedema	6	0
Oedema	16	0
Oedema peripheral	13	0
<b>Pain and discomfort NEC</b>		
Axillary pain	864	0
Chest discomfort	416	0
Chest pain	1495	0
Discomfort	117	0
Facial discomfort	1	0
Facial pain	37	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Hernia pain	1	0
Inflammatory pain	6	0
Non-cardiac chest pain	2	0
Pain	2473	0
Tenderness	197	0
Visceral pain	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	138	0
Adverse event	1	0
Adverse reaction	10	0
Drug ineffective	12	0
Drug intolerance	1	0
Immediate post-injection reaction	2	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	2	0
<b>Ulcers NEC</b>		
Ulcer	5	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	10	0
Vaccination site bruising	25	0
Vaccination site discolouration	2	0
Vaccination site discomfort	8	0
Vaccination site eczema	1	0
Vaccination site erythema	292	0
Vaccination site haemorrhage	3	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	19	0
Vaccination site inflammation	13	0
Vaccination site irritation	2	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site macule	1	0
Vaccination site mass	78	0
Vaccination site movement impairment	18	0
Vaccination site oedema	1	0
Vaccination site pain	351	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	69	0
Vaccination site rash	143	0
Vaccination site reaction	8	0
Vaccination site scar	1	0
Vaccination site swelling	192	0
Vaccination site urticaria	13	0
Vaccination site vesicles	3	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site warmth	133	0
<b><i>Withdrawal and rebound effects</i></b>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	7	0
<b>General disorders SOC TOTAL</b>	<b>33554</b>	<b>20</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	5	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	1	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	1	0
Jaundice	5	0
Jaundice cholestatic	2	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Hepatic cyst	1	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	0
<i><b>Hepatic vascular disorders</b></i>		
Portal vein thrombosis	2	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	11	0
Liver tenderness	1	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	2	0
Drug-induced liver injury	1	0
Hepatic steatosis	1	0
Hepatitis	2	0
Immune-mediated hepatitis	1	0
Liver injury	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<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	321	0
Infusion related hypersensitivity reaction	12	0
Multiple allergies	3	0
Serum sickness	3	0
Serum sickness-like 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	12	0
Drug hypersensitivity	12	0
Food allergy	2	0
Milk allergy	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	65	0
Anaphylactic shock	7	0
Anaphylactoid reaction	6	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	49	0
Immune system disorder	3	0
Immune-mediated adverse reaction	1	0
Sensitisation	4	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>549</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	6	0
Diverticulitis	4	0
Dysentery	1	0
Gastroenteritis	5	0
<b><i>Bacterial infections NEC</i></b>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Bacterial infection	3	0
Cellulitis	72	0
Folliculitis	1	0
Injection site cellulitis	2	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	4	0
<b><i>Bone and joint infections</i></b>		
Arthritis infective	1	0
<b><i>Borrelial infections</i></b>		
Relapsing fever	1	0
<b><i>Breast infections</i></b>		
Breast abscess	1	0
Mastitis	8	0
<b><i>Candida infections</i></b>		
Candida infection	7	0
Oral candidiasis	3	0
Vulvovaginal candidiasis	8	0
<b><i>Cardiac infections</i></b>		
Endocarditis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Central nervous system infection	1	0
Meningitis	3	0
Meningitis aseptic	1	0
<b><i>Coronavirus infections</i></b>		
Asymptomatic COVID-19	1	0
COVID-19	215	0
COVID-19 pneumonia	5	0
Post-acute COVID-19 syndrome	1	0
Suspected COVID-19	3	0
<b><i>Coxiella infections</i></b>		
Q fever	7	0
<b><i>Cytomegaloviral infections</i></b>		
Cytomegalovirus infection	1	0
Cytomegalovirus infection reactivation	2	0
<b><i>Dental and oral soft tissue infections</i></b>		
Gingivitis	2	0
Sialoadenitis	1	0
Tooth abscess	1	0
Tooth infection	2	0
<b><i>Ear infections</i></b>		
Ear infection	9	0
Labyrinthitis	11	0
Otitis externa	1	0
<b><i>Ectoparasitic infestations</i></b>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Acarodermatitis	1	0
Lice infestation	1	0
<b>Enteroviral infections NEC</b>		
Hand-foot-and-mouth disease	1	0
<b>Epstein-Barr viral infections</b>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	2	0
<b>Eye and eyelid infections</b>		
Conjunctivitis	13	0
Eye infection	3	0
Eyelid boil	1	0
Hordeolum	2	0
<b>Female reproductive tract infections</b>		
Vaginal infection	1	0
<b>Flaviviral infections</b>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<b>Fungal infections NEC</b>		
Fungal infection	3	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
<b>Fusobacterium infections</b>		
Necrotising ulcerative gingivostomatitis	1	0
<b>Herpes viral infections</b>		
Eczema herpeticum	2	0
Genital herpes	13	0
Herpes ophthalmic	1	0
Herpes simplex	6	0
Herpes simplex reactivation	1	0
Herpes zoster	98	0
Herpes zoster oticus	2	0
Nasal herpes	1	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	90	0
Varicella	4	0
Varicella zoster virus infection	1	0
<b>Infections NEC</b>		
Abscess	1	0
Abscess limb	2	0
Abscess rupture	1	0
Infection	84	0
Injection site infection	1	0
Localised infection	19	0
Lymph gland infection	1	0
Lymph node abscess	2	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	5	0
Vaccine breakthrough infection	1	0
Vestibulitis	1	0
Wound infection	1	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
<b><i>Infectious disorders carrier</i></b>		
SARS-CoV-2 carrier	2	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	551	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Atypical pneumonia	1	0
Bronchitis	6	0
Lower respiratory tract infection	58	1
Pleural infection	1	0
Pneumonia	12	1
<b><i>Male reproductive tract infections</i></b>		
Epididymitis	1	0
Orchitis	3	0
<b><i>Mumps viral infections</i></b>		
Mumps	1	0
<b><i>Nematode infections</i></b>		
Enterobiasis	1	0
<b><i>Rabies viral infections</i></b>		
Rabies	1	1
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	1	0
<b><i>Rubella viral infections</i></b>		
Rubella	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Intestinal sepsis	1	0
Sepsis	4	0
Septic shock	1	0
Urosepsis	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Acne pustular	1	0
Eczema infected	1	0
Impetigo	6	0
Infected skin ulcer	1	0
Pustule	9	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	12	0
Vaccination site pustule	1	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	9	0
<b><i>Streptococcal infections</i></b>		
Pharyngitis streptococcal	1	0
<b><i>Tinea infections</i></b>		
Body tinea	3	0
Tinea infection	1	0
<b><i>Tuberculous infections</i></b>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
<b><i>Upper respiratory tract infections</i></b>		
Acute sinusitis	1	0
Chronic sinusitis	1	0



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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Laryngitis	4	0
Nasopharyngitis	287	0
Peritonsillar abscess	1	0
Pharyngitis	4	0
Rhinitis	6	0
Sinusitis	28	0
Tonsillitis	14	0
Upper respiratory tract infection	2	0
<b>Urinary tract infections</b>		
Cystitis	10	0
Kidney infection	4	0
Urinary tract infection	33	0
<b>Vascular infections</b>		
Lymphangitis	2	0
<b>Viral infections NEC</b>		
Conjunctivitis viral	1	0
Gastroenteritis viral	3	0
Meningitis viral	2	0
Post viral fatigue syndrome	6	0
Sweating fever	55	0
Vestibular neuronitis	2	0
Viral infection	6	0
Viral labyrinthitis	2	0
Viral pharyngitis	6	0
Viral rash	7	0
<b>Infections SOC TOTAL</b>	<b>1968</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Oral contusion	1	0
Palate injury	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	1	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Anaesthetic complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotrauma	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Joint injury	1	0
<b><i>Cardiovascular injuries</i></b>		
Vascular injury	1	0
<b><i>Cerebral injuries NEC</i></b>		
Concussion	8	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	2	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	14	0
<b><i>Cranial nerve injuries</i></b>		
Optic nerve injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	24	0
Foetal exposure during pregnancy	9	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	523	0
Maternal exposure during pregnancy	242	0
Maternal exposure timing unspecified	1	0
<b><i>Exposures to agents or circumstances NEC</i></b>		
Exposure to SARS-CoV-2	3	0
<b><i>Eye injuries NEC</i></b>		
Eye contusion	2	0
Eye injury	2	0
<b><i>Fractures and dislocations NEC</i></b>		
Compression fracture	1	0
Joint dislocation	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Procedural vomiting	1	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	8	0
Heat stroke	8	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	8	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	12	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	3	0
Ligament sprain	2	0
Muscle injury	4	0

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Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Muscle strain	4	0
Tendon injury	1	0
Tendon rupture	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	17	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Procedural dizziness	4	0
<b><i>Non-occupational environmental exposures</i></b>		
Exposure to extreme temperature	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Arthropod bite	4	0
Bite	1	0
Electric shock	6	0
Fall	30	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
<b><i>Non-site specific procedural complications</i></b>		
Incision site pain	1	0
Infusion related reaction	1	0
Injection related reaction	24	0
Post procedural complication	1	0
Post procedural erythema	1	0
Procedural pain	1	0
<b><i>Occupational exposures</i></b>		
Occupational exposure to toxic agent	1	0
<b><i>Off label uses</i></b>		
Off label use	16	0
<b><i>Overdoses NEC</i></b>		
Overdose	6	0
<b><i>Peripheral nerve injuries</i></b>		
Sciatic nerve injury	1	0
Ulnar nerve injury	1	0
<b><i>Poisoning and toxicity</i></b>		
Systemic toxicity	1	0
Toxicity to various agents	1	0
<b><i>Product administration errors and issues</i></b>		
Accidental overdose	65	0
Expired product administered	28	0
Extra dose administered	3	0
Inappropriate schedule of product administration	46	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	9	0
Incorrect route of product administration	2	0
Poor quality product administered	1	0
Product administered at inappropriate site	4	0
Product administration interrupted	1	0
Product dose omission issue	5	0

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Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Wrong product administered	1	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	1	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	1	0
<b>Radiation injuries</b>		
Sunburn	14	0
<b>Renal and urinary tract injuries NEC</b>		
Bladder injury	1	0
<b>Site specific injuries NEC</b>		
Back injury	1	0
Head injury	9	0
Limb injury	37	0
<b>Skin injuries NEC</b>		
Contusion	314	0
Scar	11	0
Scratch	2	0
Skin abrasion	1	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<b>Skull fractures, facial bone fractures and dislocations</b>		
Jaw fracture	1	0
<b>Spinal cord injuries NEC</b>		
Spinal cord injury cervical	1	0
<b>Stoma complications</b>		
Stoma site discomfort	1	0
Stoma site oedema	1	0
<b>Thermal burns</b>		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	12	0
Thermal burns of eye	5	0
<b>Thoracic cage fractures and dislocations</b>		
Sternal fracture	1	0
<b>Vaccination related complications</b>		
Vaccination complication	15	0
<b>Injuries SOC TOTAL</b>	<b>1637</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal medulla tests</i></b>		
Norepinephrine increased	2	0
<b><i>Bacteria identification and serology (excl mycobacteria)</i></b>		
Campylobacter test positive	1	0
<b><i>Blood counts NEC</i></b>		
Full blood count abnormal	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Oxygen consumption decreased	1	0
Oxygen saturation	2	0
Oxygen saturation decreased	12	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose	1	0
Blood glucose decreased	2	0
Blood glucose increased	6	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	3	0
Heart sounds	4	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Ejection fraction decreased	1	0
<b><i>Central nervous system imaging procedures</i></b>		
Computerised tomogram head	1	0
<b><i>Cholesterol analyses</i></b>		
Low density lipoprotein increased	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Bleeding time	1	0
Bleeding time abnormal	1	0
Blood fibrinogen	1	0
Coagulation time shortened	1	0
Fibrin D dimer increased	3	0
<b><i>ECG investigations</i></b>		
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
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	12	0
<b><i>Fertility analyses</i></b>		
Semen analysis abnormal	1	0
<b><i>Foetal and neonatal diagnostic procedures</i></b>		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<b><i>Fungus identification and serology</i></b>		
Fungal test	1	0
<b><i>Gastrointestinal and abdominal imaging procedures</i></b>		
X-ray with contrast upper gastrointestinal tract	1	0
<b><i>Gastrointestinal function diagnostic procedures</i></b>		
Gastric pH decreased	1	0
<b><i>Haematological analyses NEC</i></b>		
Blood viscosity increased	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	227	0
Heart rate abnormal	19	0
Heart rate decreased	13	0
Heart rate increased	360	0
Heart rate irregular	66	0
Heart rate variability decreased	1	0
Maximum heart rate increased	1	0
Sinus rhythm	2	0
<b><i>Imaging procedures NEC</i></b>		
X-ray	1	0
<b><i>Investigations NEC</i></b>		
Blood test abnormal	4	0
Polymerase chain reaction positive	2	0
<b><i>Liver function analyses</i></b>		
Alanine aminotransferase increased	5	0
Aspartate aminotransferase	2	0
Bile output	3	0
Blood bilirubin increased	1	0
Liver function test abnormal	7	0
Liver function test increased	1	0
Transaminases increased	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood calcium increased	1	0
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Urine copper	1	0
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
Bone scan	1	0
<b><i>Musculoskeletal and soft tissue tests NEC</i></b>		
Tender joint count	1	0
<b><i>Neurologic diagnostic procedures</i></b>		
Coma scale abnormal	2	0
Electromyogram abnormal	1	0
Sensory level	1	0
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Visual tracking test	1	0
Visual tracking test abnormal	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	94	0
Body temperature abnormal	8	0
Body temperature decreased	13	0
Body temperature fluctuation	23	0
Body temperature increased	109	0
Breath sounds	1	0
Grip strength	1	0
Grip strength decreased	2	0
Head lag	3	0
Lymph node palpable	4	0
Muscle strength abnormal	1	0
Palpatory finding abnormal	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Product residue present	1	0
Respiratory rate	4	0
Respiratory rate decreased	6	0
Respiratory rate increased	10	0
Skin temperature	21	0
Temperature difference of extremities	4	0
Weight decreased	19	0
Weight increased	10	0
<b><i>Pituitary analyses anterior</i></b>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	1	0
<b><i>Platelet analyses</i></b>		
Platelet count decreased	9	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	8	0
<b><i>Red blood cell analyses</i></b>		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
<b><i>Renal function analyses</i></b>		
Blood creatinine increased	1	0
<b><i>Reproductive hormone analyses</i></b>		
False negative pregnancy test	1	0
Pregnancy test	1	0
<b><i>Reproductive organ and breast histopathology procedures</i></b>		
Smear cervix	1	0
<b><i>Reproductive organ and breast imaging procedures</i></b>		
Hysteroscopy	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume increased	2	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	1	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	4	0
<b><i>Therapeutic drug monitoring analyses</i></b>		
Analgesic drug level	5	0
<b><i>Thyroid analyses</i></b>		
Tri-iodothyronine decreased	1	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood lactate dehydrogenase increased	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine	5	0
Blood urine present	24	0
Protein urine	1	0
pH urine	1	0
<b><i>Urinary tract function analyses NEC</i></b>		
Urine output	10	0
Urine output decreased	1	0
<b><i>Urinary tract imaging procedures</i></b>		
Bladder scan	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure abnormal	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Blood pressure decreased	11	0
Blood pressure diastolic increased	1	0
Blood pressure increased	30	0
Blood pressure measurement	6	0
Blood pressure normal	1	0
<b><i>Virus identification and serology</i></b>		
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	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	6	0
<b><i>Vitamin analyses</i></b>		
Blood folate decreased	1	0
<b><i>White blood cell analyses</i></b>		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>1309</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	2	0
Decreased appetite	386	0
Food craving	2	0
Food refusal	4	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	7	0
Salt craving	1	0
<i><b>Copper metabolism disorders</b></i>		
Copper deficiency	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	3	0
Diabetes mellitus inadequate control	4	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	2	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	19	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	1	0
Food intolerance	2	0
Gluten sensitivity	1	0
Histamine intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	2	0
Abnormal weight gain	7	0
Feeding disorder	45	0
Food aversion	5	0
Neonatal insufficient breast milk syndrome	3	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	7	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	9	0
<i><b>Potassium imbalance</b></i>		
Hypokalaemia	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	98	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	9	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Folate deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>634</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	45	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	8	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthrits	1	0
<i><b>Bone disorders NEC</b></i>		
Bone erosion	1	0
Jaw cyst	1	0
Jaw disorder	1	0
Osteitis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	94	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	91	0
Spinal pain	16	0
<i><b>Bursal disorders</b></i>		
Bursitis	21	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	16	0
<i><b>Connective tissue disorders NEC</b></i>		
Polymyalgia rheumatica	3	0
Reynold's syndrome	2	0
<i><b>Extremity deformities</b></i>		
Hand deformity	1	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	2	0
<i><b>Joint related disorders NEC</b></i>		
Hypermobility syndrome	1	0
Joint lock	7	0
Periarthritis	41	0
Rotator cuff syndrome	4	0
Temporomandibular joint syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	2289	0
Joint effusion	1	0
Joint noise	3	0
Joint range of motion decreased	1	0
Joint stiffness	65	0
Joint swelling	69	0
Joint vibration	1	0
Joint warmth	5	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	2	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	8	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	20	0
Myalgia	3061	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle atrophy	2	0
Muscle discomfort	2	0
Muscle fatigue	93	0
Muscle haemorrhage	1	0
Muscle spasms	441	0
Muscle swelling	15	0
Muscle tightness	25	0
Muscle twitching	78	0
Myosclerosis	1	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	3	0
Nuchal rigidity	4	0
Trismus	8	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	188	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Growth retardation	1	0
Limb mass	1	0
Mastication disorder	2	0
Mobility decreased	17	0
Muscle contracture	1	0
Musculoskeletal disorder	2	0
Musculoskeletal stiffness	427	0
Weight bearing difficulty	1	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Facial asymmetry	2	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Dupuytren's contracture	1	0
Fasciitis	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	736	0
Flank pain	17	0
Limb discomfort	356	0
Musculoskeletal chest pain	57	0
Musculoskeletal discomfort	17	0
Musculoskeletal pain	20	0
Neck pain	433	0
Pain in extremity	3603	0
Sacral pain	1	0
<b><i>Myopathies</i></b>		
Rhabdomyolysis	1	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	5	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	1	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	11	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	56	0
Fluctuance	1	0
Groin pain	24	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Neck mass	12	0
Soft tissue swelling	2	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	3	0
Arthritis reactive	11	0
Axial spondyloarthritis	1	0
<b>Synovial disorders</b>		
Synovial cyst	5	0
<b>Tendon disorders</b>		
Tendon pain	3	0
Tendonitis	6	0
Trigger finger	3	0
<b>Trunk deformities</b>		
Shoulder deformity	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>12595</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>B-cell lymphomas NEC</b></i>		
B-cell lymphoma stage II	1	0
B-cell lymphoma stage III	1	0
<i><b>Breast and nipple neoplasms benign</b></i>		
Benign breast neoplasm	1	0
<i><b>Breast and nipple neoplasms malignant</b></i>		
Breast cancer	3	0
<i><b>Cardiovascular neoplasms benign</b></i>		
Haemangioma	1	0
<i><b>Leukaemias NEC</b></i>		
Leukaemia	1	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	8	0
<i><b>Mediastinal neoplasms malignancy unspecified NEC</b></i>		
Good syndrome	1	0
<i><b>Metastases to specified sites</b></i>		
Metastases to lymph nodes	1	0
<i><b>Metastases to unknown and unspecified sites</b></i>		
Metastasis	1	0
<i><b>Oesophageal neoplasms malignant</b></i>		
Oesophageal carcinoma	1	0
<i><b>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</b></i>		
Tonsil cancer	2	0
<i><b>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</b></i>		
Bronchial carcinoma	1	0
<i><b>Skin neoplasms benign</b></i>		
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	4	0
<i><b>Small intestinal neoplasms malignant</b></i>		
Small intestine adenocarcinoma	1	0
<i><b>Soft tissue neoplasms benign NEC</b></i>		
Lipoma	1	0
<i><b>Urinary tract neoplasms unspecified malignancy NEC</b></i>		
Renal neoplasm	1	0
<i><b>Uterine neoplasms benign</b></i>		
Uterine leiomyoma	2	0
<b>Neoplasms SOC TOTAL</b>	<b>37</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Abnormal sleep-related events</i></b>		
Sleep paralysis	5	0
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	1	0
<b><i>Acute polyneuropathies</i></b>		
Guillain-Barre syndrome	10	0
<b><i>Autonomic nervous system disorders</i></b>		
Orthostatic intolerance	3	0
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Brain stem infarction	1	0
Cerebral haemorrhage	3	1
Cerebral infarction	1	0
Cerebrovascular accident	24	1
Haemorrhage intracranial	2	0
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	2	0
Subarachnoid haemorrhage	5	0
<b><i>Central nervous system inflammatory disorders NEC</i></b>		
Central nervous system inflammation	2	0
<b><i>Central nervous system vascular disorders NEC</i></b>		
Cerebral congestion	1	0
<b><i>Cerebrovascular venous and sinus thrombosis</i></b>		
Cerebral venous sinus thrombosis	3	0
<b><i>Chronic polyneuropathies</i></b>		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
Demyelinating polyneuropathy	1	0
<b><i>Coordination and balance disturbances</i></b>		
Ataxia	2	0
Balance disorder	74	0
Coordination abnormal	5	0
Dysstasia	11	0
Nystagmus	2	0
<b><i>Cortical dysfunction NEC</i></b>		
Aphasia	5	0
<b><i>Demyelinating disorders NEC</i></b>		
Demyelination	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Depressed level of consciousness	12	0
Lethargy	458	0
Loss of consciousness	243	0
Somnolence	246	0
Stupor	1	0
Syncope	1030	0
<b><i>Disturbances in sleep phase rhythm</i></b>		
Delayed sleep phase	1	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Akathisia	1	0
Bradykinesia	4	0
Clumsiness	4	0
Dyskinesia	11	0
Extrapyramidal disorder	2	0
Fine motor delay	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Fine motor skill dysfunction	4	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	14	0
Motor dysfunction	3	0
Movement disorder	12	0
Psychomotor hyperactivity	2	0
<b>Dystonias</b>		
Dystonia	1	0
<b>Encephalitis NEC</b>		
Noninfective encephalitis	1	0
<b>Eye movement disorders</b>		
IVth nerve paresis	1	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	83	0
Facial paralysis	45	0
Facial paresis	12	0
Facial spasm	7	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	5	0
<b>Glossopharyngeal nerve disorders</b>		
Glossopharyngeal neuralgia	1	0
<b>Headaches NEC</b>		
Cluster headache	60	0
Cold-stimulus headache	11	0
Drug withdrawal headache	2	0
Headache	7534	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	95	0
Tension headache	154	0
Thunderclap headache	2	0
Vascular headache	6	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	1	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	3	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	10	0
<b>Memory loss (excl dementia)</b>		
Amnesia	41	0
Memory impairment	30	0
Transient global amnesia	1	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	17	0
Disturbance in attention	77	0
Mental impairment	14	0
<b>Migraine headaches</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Basilar migraine	1	0
Hemiplegic migraine	6	0
Migraine	752	0
Migraine with aura	43	0
Migraine without aura	3	0
Retinal migraine	4	0
Typical aura without headache	1	0
Vestibular migraine	2	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	5	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	4	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0
Multiple sclerosis	1	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	4	0
<b>Muscle tone abnormal</b>		
Drop attacks	1	0
Hypotonia	10	0
Stiff leg syndrome	3	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	2	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	26	0
Narcolepsy	1	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	4	0
Psychomotor skills impaired	1	0
<b>Neurologic visual problems NEC</b>		
Tunnel vision	11	0
<b>Neurological signs and symptoms NEC</b>		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	3031	0
Dizziness exertional	10	0
Dizziness postural	199	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	54	0
Neurological symptom	7	0
Persistent postural-perceptual dizziness	2	0
Presyncope	244	0
Tongue biting	1	0
Unresponsive to stimuli	12	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	2	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	38	0
Hyposmia	2	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Parosmia	37	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	4	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	5	0
Burning sensation	107	0
Dysaesthesia	1	0
Formication	7	0
Hemianaesthesia	2	0
Hyperaesthesia	52	0
Hypoaesthesia	604	0
Paraesthesia	863	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	2	0
Hemiparesis	4	0
Hemiplegia	7	0
Monoparesis	20	0
Monoplegia	24	0
Paralysis	28	0
Paraparesis	1	0
Paresis	2	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	11	0
Reduced facial expression	1	0
<b>Peripheral neuropathies NEC</b>		
Autoimmune neuropathy	2	0
Neuralgic amyotrophy	3	0
Neuritis	1	0
Neuropathy peripheral	13	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	2	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	20	0
Febrile convulsion	5	0
Myoclonic epilepsy	1	0
Partial seizures	7	0
Psychogenic seizure	1	0
Seizure	169	0
Seizure anoxic	1	0
Seizure cluster	1	0
Status epilepticus	27	0
Tonic clonic movements	3	0
Tonic convulsion	5	0
<b>Sensory abnormalities NEC</b>		
Ageusia	80	0
Allodynia	2	0
Aura	2	0
Complex regional pain syndrome	1	0
Dysgeusia	211	0
Electric shock sensation	11	0
Hypogeusia	1	0
Neuralgia	120	0
Post herpetic neuralgia	2	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Restless legs syndrome	40	0
Sensory disturbance	16	0
Sensory loss	28	0
Taste disorder	44	0
Vibratory sense increased	1	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	5	0
<b>Speech and language abnormalities</b>		
Dysarthria	28	0
Incoherent	9	0
Slow speech	5	0
Speech disorder	12	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	3	0
Radiculopathy	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	16	0
<b>Tremor (excl congenital)</b>		
Essential tremor	1	0
Head titubation	2	0
Tremor	595	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	5	0
<b>Nervous system disorders SOC TOTAL</b>	<b>18227</b>	<b>2</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	53	0
<i><b>Foetal complications NEC</b></i>		
Foetal hypokinesia	3	0
Hydrops foetalis	1	0
<i><b>Foetal growth complications</b></i>		
Foetal growth restriction	1	0
<i><b>Gestational age and weight conditions</b></i>		
Premature baby	1	0
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Premature separation of placenta	1	0
<i><b>Labour onset and length abnormalities</b></i>		
Premature labour	4	0
<i><b>Maternal complications of labour NEC</b></i>		
Uterine atony	1	0
Uterine hypertonus	2	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
Somatic symptom disorder of pregnancy	1	0
<i><b>Multiple pregnancies</b></i>		
Twin pregnancy	1	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Live birth	2	0
Pregnancy	5	0
<i><b>Postpartum complications NEC</b></i>		
Postpartum haemorrhage	1	0
<i><b>Pregnancy complicated by maternal disorders</b></i>		
Gestational diabetes	1	0
<i><b>Stillbirth and foetal death</b></i>		
Stillbirth	1	0
<i><b>Umbilical cord complications</b></i>		
Umbilical cord thrombosis	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>85</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device expulsion	1	0
Device leakage	1	0
<b><i>Device malfunction events NEC</i></b>		
Thrombosis in device	2	0
Undersensing	1	0
<b><i>Manufacturing materials issues</i></b>		
Manufacturing materials issue	1	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination physical	8	0
Suspected product contamination	1	0
<b><i>Product label issues</i></b>		
Product label issue	1	0
<b><i>Product physical issues</i></b>		
Product after taste	1	0
Product taste abnormal	1	0
<b><i>Product quality issues NEC</i></b>		
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	2	0
<b>null SOC TOTAL</b>	<b>23</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	5	0
Breath holding	2	0
Staring	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	2	0
Flat affect	4	0
Inappropriate affect	3	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	1	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	1	0
Separation anxiety disorder	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	21	0
Anxiety	230	0
Nervousness	42	0
Stress	20	0
Tension	9	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	4	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	1	0
Disinhibition	1	0
Impatience	1	0
Paranoia	6	0
Personality change	2	0
Social avoidant behaviour	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Distractibility	1	0
Mental fatigue	49	0
<b><i>Communications disorders</i></b>		
Mutism	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	194	0
Disorientation	76	0
<b><i>Deliria</i></b>		
Delirium	47	0
<b><i>Delusional disorders</i></b>		
Alice in wonderland syndrome	1	0
<b><i>Delusional symptoms</i></b>		
Delusion	3	0
Delusion of parasitosis	1	0
<b><i>Depressive disorders</i></b>		
Depression	81	0
Depression suicidal	4	0
Major depression	3	0
Mixed anxiety and depressive disorder	1	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	2	0
Dissociation	13	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	4	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Insomnia	427	0
Middle insomnia	13	0
Terminal insomnia	13	0
<b>Dyssomnias</b>		
Poor quality sleep	89	0
<b>Eating disorders NEC</b>		
Binge eating	1	0
<b>Emotional and mood disturbances NEC</b>		
Anger	12	0
Emotional disorder	21	0
Emotional distress	11	0
Emotional poverty	1	0
Euphoric mood	12	0
Frustration tolerance decreased	1	0
Irritability	51	0
Mood altered	14	0
<b>Factitious disorders</b>		
Factitious disorder	1	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Fear	4	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
<b>Fluctuating mood symptoms</b>		
Mood swings	14	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	114	0
Hallucination, auditory	6	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	4	0
Hallucinations, mixed	1	0
Somatic hallucination	1	0
<b>Increased physical activity levels</b>		
Restlessness	57	0
<b>Mental disorders NEC</b>		
Mental disorder	4	0
<b>Mood alterations with depressive symptoms</b>		
Depressed mood	86	0
Feeling of despair	5	0
Negative thoughts	1	0
Sense of a foreshortened future	1	0
Tearfulness	6	0
<b>Mood alterations with manic symptoms</b>		
Mania	4	0
<b>Mood disorders NEC</b>		
Apathy	11	0
Listless	7	0
<b>Narcolepsy and associated conditions</b>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Hypnagogic hallucination	1	0
<b>Orgasmic disorders and disturbances</b>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<b>Panic attacks and disorders</b>		
Limited symptom panic attack	1	0
Panic attack	50	0
Panic reaction	10	0
<b>Paraphilias and paraphilic disorders</b>		
Exhibitionism	1	0
<b>Parasomnias</b>		
Abnormal dreams	35	0
Abnormal sleep-related event	1	0
Nightmare	54	0
Sleep inertia	1	0
Sleep talking	2	0
Sleep terror	5	0
Somnambulism	1	0
<b>Perception disturbances NEC</b>		
Autoscopy	3	0
Derealisation	3	0
Illusion	1	0
<b>Psychiatric elimination disorders</b>		
Enuresis	13	0
<b>Psychiatric symptoms NEC</b>		
Hypervigilance	2	0
Psychiatric symptom	3	0
Psychological trauma	1	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	1	0
Psychotic disorder	2	0
<b>Sexual desire disorders</b>		
Libido decreased	6	0
Libido increased	1	0
Loss of libido	2	0
<b>Sleep disorders NEC</b>		
Sleep disorder	70	0
<b>Somatic symptom disorders</b>		
Conversion disorder	4	0
Habit cough	7	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	1	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	3	0
Lack of spontaneous speech	1	0
<b>Stereotypies and automatisms</b>		
Bruxism	4	0
Head banging	6	0
<b>Stress disorders</b>		
Acute stress disorder	1	0
<b>Substance related and addictive disorders</b>		
Alcoholism	1	0
<b>Suicidal and self-injurious behaviour</b>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	17	0
Suicide attempt	1	0
<b>Thinking disturbances</b>		
Bradyphrenia	4	0
Intrusive thoughts	1	0
Tachyphrenia	3	0
Thinking abnormal	4	0
Thought blocking	1	0
<b>Tic disorders</b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>2181</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder irritation	1	0
Bladder pain	9	0
Dysuria	9	0
Incontinence	10	0
Micturition urgency	11	0
Pollakiuria	40	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	11	0
Urinary retention	4	0
Urinary straining	1	0
Urine flow decreased	1	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	2	0
Urinary bladder haemorrhage	2	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	1	0
<i><b>Genitourinary tract infections and inflammations NEC</b></i>		
Urinary tract inflammation	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis acute	1	0
IgA nephropathy	2	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	1	0
Hypertonic bladder	2	0
Loss of bladder sensation	1	0
<i><b>Nephritis NEC</b></i>		
Nephritis	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	5	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	2	0
Renal impairment	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	19	0
Haematuria	9	0
Loin pain haematuria syndrome	1	0
Urine abnormality	5	0
Urine odour abnormal	3	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	8	0
Nocturia	1	0
Renal pain	97	0
Urinary tract pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>268</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	4	0
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	4	0
Breast mass	16	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	3	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	2	0
Breast discomfort	2	0
Breast haemorrhage	1	0
Breast oedema	1	0
Breast pain	129	0
Breast swelling	22	0
Breast tenderness	13	0
Nipple pain	2	0
Nipple swelling	2	0
<i><b>Cervix disorders NEC</b></i>		
Ectropion of cervix	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	13	0
Erection increased	1	0
Nocturnal emission	1	0
Organic erectile dysfunction	10	0
Painful ejaculation	1	0
Priapism	1	0
Spontaneous penile erection	1	0
<i><b>Gender disorders</b></i>		
Feminisation acquired	1	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	2	0
Lactation disorder	3	0
Lactation puerperal increased	2	0
Suppressed lactation	9	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	9	0
Premature menopause	3	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	16	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	426	0
Intermenstrual bleeding	227	0
Menstrual discomfort	2	0
Menstrual disorder	357	0
Menstruation irregular	578	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	20	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Premenstrual syndrome	15	0
Withdrawal bleed	2	0
<b>Menstruation with decreased bleeding</b>		
Amenorrhoea	81	0
Hypomenorrhoea	100	0
Menstruation delayed	699	0
Oligomenorrhoea	25	0
<b>Menstruation with increased bleeding</b>		
Heavy menstrual bleeding	961	0
Menometrorrhagia	8	0
Polymenorrhoea	143	0
<b>Ovarian and fallopian tube cysts and neoplasms</b>		
Ovarian cyst	7	0
Polycystic ovaries	9	0
<b>Ovarian and fallopian tube disorders NEC</b>		
Fallopian tube spasm	1	0
Ovulation pain	17	0
Premature ovulation	1	0
<b>Pelvis and broad ligament disorders NEC</b>		
Adnexa uteri pain	19	0
Pelvic haemorrhage	2	0
<b>Penile disorders NEC (excl erection and ejaculation)</b>		
Penile pain	1	0
Penis disorder	3	0
<b>Prostate and seminal vesicles infections and inflammations</b>		
Prostatitis	2	0
<b>Prostatic signs, symptoms and disorders NEC</b>		
Prostatic pain	1	0
<b>Reproductive tract disorders NEC (excl neoplasms)</b>		
Genital blister	1	0
Genital haemorrhage	3	0
Genital paraesthesia	1	0
Genital ulceration	1	0
<b>Reproductive tract signs and symptoms NEC</b>		
Genital odour	1	0
Genital pain	2	0
Pelvic discomfort	1	0
Pelvic pain	27	0
<b>Scrotal disorders NEC</b>		
Scrotal pain	9	0
Scrotal swelling	1	0
Varicocele	2	0
<b>Sexual function and fertility disorders NEC</b>		
Infertility	3	0
Sexual dysfunction	1	0
<b>Spermatogenesis and semen disorders</b>		
Haematospermia	1	0
<b>Testicular and epididymal disorders NEC</b>		
Testicular disorder	2	0
Testicular mass	1	0
Testicular pain	21	0
Testicular swelling	5	0
<b>Uterine disorders NEC</b>		

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	15	0
Metrorrhoea	1	0
Uterine haemorrhage	11	0
Uterine pain	8	0
<b><i>Uterine neoplasms</i></b>		
Uterine polyp	1	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	14	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Vaginal cyst	1	0
Vulva cyst	1	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	304	0
Vaginal ulceration	3	0
Vulval haemorrhage	10	0
Vulval ulceration	2	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	16	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
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>4479</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	1	0
Dyspnoea	1316	0
Dyspnoea at rest	1	0
Dyspnoea exertional	6	0
Hyperventilation	11	0
Hypopnoea	24	0
Hypoventilation	1	0
Irregular breathing	5	0
Mouth breathing	1	0
Respiration abnormal	21	0
Respiratory arrest	1	1
Respiratory distress	2	0
Sleep apnoea syndrome	4	0
Tachypnoea	7	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	65	0
Asthma exercise induced	2	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	1	0
Childhood asthma	2	0
Chronic obstructive pulmonary disease	1	0
Obstructive airways disorder	1	0
Wheezing	113	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	2	0
Cough	542	0
Haemoptysis	4	0
Productive cough	35	0
Sputum discoloured	3	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Reflux laryngitis	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonitis	5	0
Pulmonary sarcoidosis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	15	0
Lower respiratory tract congestion	1	0
Pleuritic pain	1	0
Pulmonary haemorrhage	1	0
Pulmonary pain	24	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	62	0
Rhinitis allergic	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	182	0
Nasal dryness	3	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Nasal oedema	2	0
Nasal pruritus	3	0
<b><i>Paranasal sinus disorders (excl infections and neoplasms)</i></b>		
Sinonasal obstruction	4	0
Sinus congestion	13	0
Sinus disorder	3	0
<b><i>Parenchymal lung disorders NEC</i></b>		
Interstitial lung disease	2	0
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	4	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	62	0
Tonsillar erythema	3	0
Tonsillar hypertrophy	14	0
Tonsillar inflammation	1	0
<b><i>Pleural infections and inflammations</i></b>		
Pleurisy	8	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Pleural effusion	4	0
<b><i>Pulmonary hypertensions</i></b>		
Pulmonary hypertension	1	0
<b><i>Pulmonary oedemas</i></b>		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	5	0
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary embolism	47	0
Pulmonary thrombosis	3	0
<b><i>Respiratory failures (excl neonatal)</i></b>		
Respiratory failure	1	0
<b><i>Respiratory signs and symptoms NEC</i></b>		
Diaphragmalgia	3	0
Painful respiration	3	0
Respiratory symptom	2	0
Use of accessory respiratory muscles	1	0
<b><i>Respiratory tract disorders NEC</i></b>		
Allergic respiratory disease	1	0
Pulmonary mass	1	0
Respiratory disorder	2	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	17	0
Catarrh	4	0
Choking	5	0
Dry throat	28	0
Dysphonia	21	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	8	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	3	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Oropharyngeal pain	535	0
Paranasal sinus discomfort	8	0
Rhinalgia	5	0
Rhinorrhoea	162	0
Sinus pain	70	0
Sneezing	54	0
Throat irritation	40	0
Throat tightness	49	0
Upper-airway cough syndrome	4	0
Yawning	7	0
<b>Respiratory disorders SOC TOTAL</b>	<b>3708</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	36	0
Acne cystic	2	0
Dermatitis acneiform	1	0
<b><i>Alopecias</i></b>		
Alopecia	44	0
Alopecia areata	10	0
Alopecia totalis	2	0
<b><i>Angioedemas</i></b>		
Angioedema	53	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	265	0
Hidradenitis	1	0
Hyperhidrosis	908	0
Miliaria	66	0
Night sweats	283	0
<b><i>Bullous conditions</i></b>		
Blister	79	0
Blister rupture	1	0
Blood blister	3	0
Dermatitis bullous	1	0
Erythema multiforme	14	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<b><i>Connective tissue disorders</i></b>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	97	0
Pain of skin	124	0
Papule	21	0
Scab	5	0
Scar pain	5	0
Sensitive skin	136	0
Skin burning sensation	67	0
Skin discolouration	35	0
Skin discomfort	2	0
Skin disorder	2	0
Skin induration	8	0
Skin lesion	25	0
Skin necrosis	2	0
Skin odour abnormal	2	0
Skin reaction	117	0
Skin sensitisation	15	0
Skin swelling	27	0
Skin tightness	6	0
Skin warm	229	0
Yellow skin	3	0
<b><i>Dermatitis and eczema</i></b>		
Autoimmune dermatitis	1	0
Dermatitis	38	0



## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Dermatitis allergic	106	0
Dermatitis atopic	14	0
Dermatitis contact	7	0
Dyshidrotic eczema	11	0
Eczema	67	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Flagellate dermatitis	1	0
Neurodermatitis	1	0
Skin irritation	30	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	3	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	1143	0
Red man syndrome	1	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	18	0
<b><i>Hyperpigmentation disorders</i></b>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<b><i>Hypopigmentation disorders</i></b>		
Skin hypopigmentation	1	0
Vitiligo	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	1	0
Onychalgia	1	0
Onychoclasia	1	0
Onychomadesis	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	8	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	4	0
Parapsoriasis	1	0
Pityriasis rosea	12	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	18	0
<b><i>Pilar disorders NEC</i></b>		
Hair growth abnormal	2	0
Hair texture abnormal	1	0
Piloerection	16	0
Trichodynia	1	0
<b><i>Pruritus NEC</i></b>		
Itching scar	4	0
Pruritus	2393	0
<b><i>Psoriatic conditions</i></b>		
Guttate psoriasis	2	0
Psoriasis	24	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rebound psoriasis	1	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	1	0
Petechiae	21	0
Purpura	11	0
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	1	0
Rash	2752	0
Rash erythematous	1057	0
Rash macular	185	0
Rash maculo-papular	5	0
Rash morbilliform	8	0
Rash papular	179	0
Rash pruritic	578	0
Rash vesicular	8	0
<b>Rosaceas</b>		
Rosacea	2	0
<b>Scaly conditions</b>		
Pityriasis	4	0
<b>Sebaceous gland disorders</b>		
Seborrhoea	2	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	4	0
Skin mass	10	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin erosion	5	0
Skin ulcer	6	0
<b>Skin cysts and polyps</b>		
Dermal cyst	7	0
<b>Skin dystrophies</b>		
Keloid scar	2	0
Skin wrinkling	1	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	3	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	3	0
<b>Skin injuries and mechanical dermatoses</b>		
Needle track marks	2	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	3	0
Vasculitic rash	2	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	5	0
<b>Telangiectasia and related conditions</b>		
Spider naevus	1	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	1	0
Idiopathic urticaria	2	0
Mechanical urticaria	10	0
Urticaria	574	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Urticaria chronic	3	0
Urticarial vasculitis	1	0
<b>Skin disorders SOC TOTAL</b>	<b>12111</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Age related issues</b></i>		
Menarche	2	0
Menopause	8	0
Postmenopause	2	0
<i><b>Disability issues</b></i>		
Bedridden	6	0
Disability	1	0
Immobile	4	0
Impaired driving ability	2	0
Loss of personal independence in daily activities	1	0
Sight disability	2	0
<i><b>Employment issues</b></i>		
Retirement	3	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Water pollution	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	5	0
<i><b>Social issues NEC</b></i>		
Social problem	1	0
<b>Social circumstances SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Analgesia supportive care</i>		
Analgesic therapy	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	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>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	26	0
Immunisation	35	0
<i>Induced abortions</i>		
Abortion induced	1	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	2	0
<i>Limb therapeutic procedures</i>		
Finger amputation	1	0
Limb immobilisation	2	0
<i>Mastectomies</i>		
Breast conserving surgery	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Central nervous system stimulation	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	6	0
<i>Therapeutic procedures NEC</i>		
Bed rest	4	0
Botulinum toxin injection	1	0
Hospitalisation	4	0
Injection	27	0
Interchange of vaccine products	9	0
Localised alternating hot and cold therapy	2	0
Mass excision	1	0
Medication dilution	1	0
Polypectomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>140</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Hypertensive urgency	1	0
<b><i>Arterial infections and inflammations</i></b>		
Giant cell arteritis	3	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	3	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	6	0
Neurogenic shock	1	0
Shock	4	0
<b><i>Haemorrhages NEC</i></b>		
Bloody discharge	2	0
Haematoma	5	0
Haemorrhage	203	0
Internal haemorrhage	3	0
<b><i>Lymphangiopathies</i></b>		
Lymphocele	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	27	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Embolism	2	0
Embolism venous	1	0
Thrombosis	47	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Ischaemia	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Vascular pain	7	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	1	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Axillary vein thrombosis	1	0
Blue toe syndrome	5	0
Deep vein thrombosis	36	0
Pelvic venous thrombosis	1	0
Superficial vein thrombosis	2	0
Thrombophlebitis	3	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	11	0
Erythromelalgia	1	0
Flushing	53	0
Hot flush	290	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		
Extremity necrosis	1	0
Peripheral coldness	97	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	7	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
<b><i>Site specific vascular disorders NEC</i></b>		
Pallor	85	0
<b><i>Varicose veins NEC</i></b>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	4	0
Varicose vein ruptured	1	0
<b><i>Vascular hypertensive disorders NEC</i></b>		
Hypertension	92	0
Prehypertension	1	0
White coat hypertension	1	0
<b><i>Vascular hypotensive disorders</i></b>		
Capillary leak syndrome	1	0
Hypotension	92	0
Orthostatic hypotension	5	0
<b><i>Vasculitides NEC</i></b>		
Vasculitis	4	0
<b><i>Vena caval embolism and thrombosis</i></b>		
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1127</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>112011</b>	<b>30</b>
<b>TOTAL REPORTS</b>	<b>33630</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>30</b>