

COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 31-Mar-2022
Data Lock Date: 30-Mar-2022 18:30:05

All UK spontaneous reports received up to and including 23/02/2021 for COVID-19 vaccine Moderna.

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	12	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	342	0
Lymph node ulcer	1	0
Lymphadenitis	26	0
Lymphadenopathy	2029	0
Lymphatic disorder	1	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	3	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	9	0
Thrombocytopenia	29	0
Thrombocytopenic purpura	2	0
Blood disorders SOC TOTAL	2485	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	3	0
Bundle branch block left	1	0
Bundle branch block right	2	0
Sinoatrial block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	17	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	4	0
Palpitations	1631	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	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	6	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	1	0
Acute myocardial infarction	2	0
Angina pectoris	62	0
Angina unstable	2	0
Myocardial infarction	35	2
<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 dysfunction	3	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
Myocardial oedema	1	0
<i>Noninfectious myocarditis</i>		
Hypersensitivity myocarditis	1	0
Myocarditis	211	0
<i>Noninfectious pericarditis</i>		
Pericarditis	122	0
Pleuropericarditis	1	0
<i>Pericardial disorders NEC</i>		

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Cardiac disorders Cardiac disorders cont'd		
Pericardial effusion	3	0
Pericardial rub	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	29	0
Bradycardia	14	0
Cardiac fibrillation	1	0
Cardiac flutter	133	0
Extrasystoles	48	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachyarrhythmia	3	0
Tachycardia	723	1
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	34	0
Atrial flutter	11	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	11	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	6	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	15	4
Ventricular extrasystoles	4	0
Ventricular tachycardia	6	0
Cardiac disorders SOC TOTAL	3182	8

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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
Congenital disorders SOC TOTAL	10	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	293	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	51	0
Deafness neurosensory	1	0
Deafness transitory	1	0
Deafness unilateral	7	0
Hypoacusis	41	0
Sudden hearing loss	12	0
<i>Hyperacusia</i>		
Hyperacusis	9	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	3	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	19	0
Tinnitus	410	0
Vertigo	290	0
Vertigo labyrinthine	2	0
Vertigo positional	14	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	1191	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	1	0
Thyroiditis subacute	2	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>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	52	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	3	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	4	0
Vitreous detachment	2	0
Vitreous floaters	17	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	8	0
<i>Eyelid movement disorders</i>		
Blepharospasm	35	0
Eyelid ptosis	3	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	34	0
Lacrimation increased	15	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	1	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	3	0
Eye oedema	1	0
Eye pain	335	0
Eye swelling	129	0
Eyelid disorder	2	0
Eyelids pruritus	2	0
Ocular discomfort	12	0
Periorbital oedema	3	0
Periorbital swelling	19	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	3	0
Eye discharge	2	0
Eye inflammation	8	0
Eye irritation	19	0
Eye pruritus	38	0
Limbal swelling	1	0
Ocular hyperaemia	43	0

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Eye disorders Eye disorders cont'd		
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle paresis	1	0
Eye movement disorder	7	0
Gaze palsy	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	2	0
Asthenopia	28	0
Foreign body sensation in eyes	7	0
Hypoaesthesia eye	6	0
Photophobia	131	0
<i>Optic disc abnormalities NEC</i>		
Optic discs blurred	1	0
Papilloedema	1	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	2	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	2	0
<i>Pupil disorders</i>		
Mydriasis	4	0
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
Astigmatism	3	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	10	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal detachment	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Retinal oedema	1	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	5	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral disorder	1	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	2	0
<i>Visual colour distortions</i>		
Cyanopsia	1	0
Xanthopsia	2	0
<i>Visual disorders NEC</i>		
Diplopia	31	0
Halo vision	4	0
Metamorphopsia	5	0
Photopsia	31	0
Scintillating scotoma	1	0
Vision blurred	295	0
<i>Visual field disorders</i>		
Visual field defect	5	0

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Eye disorders Eye disorders cont'd		
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	34	0
Blindness transient	6	0
Blindness unilateral	1	0
Night blindness	1	0
Visual acuity reduced	3	0
Visual impairment	56	0
Eye disorders SOC TOTAL	1505	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	3	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	7	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	4	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	35	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	1126	0
Diarrhoea haemorrhagic	5	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	149	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	76	0
Flatulence	39	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	10	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	332	0
Abdominal pain lower	24	0
Abdominal pain upper	853	0
Abdominal rigidity	3	0
Abdominal tenderness	5	0
Gastrointestinal pain	35	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	41	0
Gastric dilatation	2	0
Gastrooesophageal reflux disease	38	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	2	0
Functional gastrointestinal disorder	3	0
Gastric disorder	1	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	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	168	0
Acute abdomen	1	0
Anal incontinence	3	0
Breath odour	8	0
Dysphagia	34	0
Odynophagia	8	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	9	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	19	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	18	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	4612	0
Regurgitation	1	0
Retching	30	0
Vomiting	1748	0
Vomiting projectile	21	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	3	0
Haematemesis	8	0
Haematochezia	16	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	105	0
Lip dry	9	0
Saliva altered	2	0
Salivary hypersecretion	12	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	2	0
Cheilitis	4	0
Enlarged uvula	1	0
Lip blister	3	0
Lip disorder	1	0
Oral disorder	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	90	0
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	11	0
Lip pruritus	3	0
Oral discomfort	12	0
Oral mucosal blistering	2	0
Oral mucosal eruption	3	0
Oral mucosal erythema	1	0

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Gastrointestinal disorders cont'd		
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	33	0
Oral pruritus	2	0
Paraesthesia oral	124	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	212	0
Mouth swelling	24	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	3	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland mass	1	0
Salivary gland pain	3	0
Salivary gland enlargements		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	3	0
Stomatitis and ulceration		
Aphthous ulcer	4	0
Lip ulceration	4	0
Mouth ulceration	97	0
Stomatitis	6	0
Tongue disorders		
Glossitis	7	0
Tongue disorder	10	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
Tongue signs and symptoms		
Glossodynia	30	0
Stiff tongue	1	0
Swollen tongue	93	0
Tongue blistering	3	0
Tongue coated	5	0
Tongue discolouration	3	0
Tongue discomfort	5	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
Tooth missing		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	10648	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
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
<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	4	0
<i>Asthenic conditions</i>		
Asthenia	577	0
Chronic fatigue syndrome	9	0
Decreased activity	1	0
Fatigue	6427	0
Malaise	1105	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>		
Injury associated with device	1	0
<i>Death and sudden death</i>		
Death	18	18
Sudden death	2	2
<i>Febrile disorders</i>		
Pyrexia	6736	1
<i>Feelings and sensations NEC</i>		
Chills	4032	0
Feeling abnormal	445	0
Feeling cold	395	0
Feeling drunk	17	0
Feeling hot	368	0
Feeling jittery	11	0

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General disorders General disorders cont'd		
Feeling of body temperature change	127	0
Hangover	21	0
Hunger	18	0
Sensation of blood flow	1	0
Sensation of foreign body	8	0
Temperature intolerance	22	0
Thirst	120	0
Thirst decreased	1	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	34	0
Gait inability	19	0
Loss of control of legs	4	0
General signs and symptoms NEC		
Condition aggravated	41	0
Crepitations	1	0
Crying	37	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	8	0
Foaming at mouth	2	0
General physical health deterioration	2	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	661	0
Induration	10	0
Influenza like illness	794	0
Irritability postvaccinal	1	0
Local reaction	27	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2184	0
Screaming	8	0
Secretion discharge	2	0
Swelling	1234	0
Swelling face	207	0
Implant and catheter site reactions		
Catheter site related reaction	1	0
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	201	0
Scar inflammation	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site erythema	2	0
Infusion site mass	1	0
Infusion site pain	5	0
Infusion site pruritus	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 31-Mar-2022

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site urticaria	5	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	9	0
Injection site bruising	14	0
Injection site cyst	1	0
Injection site dermatitis	1	0
Injection site discolouration	1	0
Injection site erythema	212	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	16	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	2	0
Injection site mass	209	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site oedema	6	0
Injection site pain	861	0
Injection site paraesthesia	2	0
Injection site plaque	1	0
Injection site pruritus	136	0
Injection site rash	211	0
Injection site reaction	25	0
Injection site swelling	111	0
Injection site urticaria	58	0
Injection site vesicles	3	0
Injection site warmth	104	0
Interactions		
Alcohol interaction	2	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	9	0
Mass	29	0
Nodule	6	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	2	0
Mucosal pain	1	0
Oedema mucosal	1	0
Polyp	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	8	0
Localised oedema	7	0
Oedema	18	0
Oedema peripheral	15	0
Pain and discomfort NEC		
Axillary pain	905	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Chest discomfort	453	0
Chest pain	1739	0
Discomfort	129	0
Facial discomfort	1	0
Facial pain	43	0
Hernia pain	1	0
Inflammatory pain	6	0
Non-cardiac chest pain	2	0
Pain	2693	0
Tenderness	203	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	29	0
Adverse reaction	6	0
Drug ineffective	20	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
Therapeutic product effect decreased	1	0
Therapeutic response changed	1	0
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	8	0
Ulcers NEC		
Ulcer	5	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	15	0
Vaccination site bruising	27	0
Vaccination site discolouration	2	0
Vaccination site discomfort	9	0
Vaccination site eczema	1	0
Vaccination site erythema	304	0
Vaccination site haemorrhage	6	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	22	0
Vaccination site inflammation	17	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	20	0
Vaccination site oedema	1	0
Vaccination site pain	391	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	71	0
Vaccination site rash	149	0
Vaccination site reaction	8	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site scar	1	0
Vaccination site swelling	204	0
Vaccination site urticaria	13	0
Vaccination site vesicles	3	0
Vaccination site warmth	141	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	7	0
General disorders SOC TOTAL	35947	22

Case Series Drug Analysis Print

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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
<i>Hepatic failure and associated disorders</i>		
Acute hepatic 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	3	0
Hepatic disorders SOC TOTAL	44	0

Case Series Drug Analysis Print

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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	356	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 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	14	0
Food allergy	3	0
Milk allergy	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	70	0
Anaphylactic shock	7	0
Anaphylactoid reaction	10	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
Sensitisation	4	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	603	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
Bacterial infection	3	0
Cellulitis	79	0
Folliculitis	1	0
Injection site cellulitis	2	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	9	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Encephalitis	1	0
Meningitis	4	0
Meningitis aseptic	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	1	0
COVID-19	342	0
COVID-19 pneumonia	6	0
Coronavirus infection	1	0
Post-acute COVID-19 syndrome	2	0
Suspected COVID-19	3	0
<i>Coxiella infections</i>		
Q fever	7	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus infection reactivation	2	0
Pneumonia cytomegaloviral	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	2	0
Oral infection	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Sialoadenitis	1	0
Tooth abscess	1	0
Tooth infection	2	0
Ear infections		
Ear infection	10	0
Labyrinthitis	13	0
Otitis externa	1	0
Ectoparasitic infestations		
Acarodermatitis	1	0
Lice infestation	1	0
Enteroviral infections NEC		
Hand-foot-and-mouth disease	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	2	0
Eye and eyelid infections		
Chorioretinitis	1	0
Conjunctivitis	13	0
Eye infection	3	0
Eyelid boil	1	0
Hordeolum	4	0
Female reproductive tract infections		
Vaginal infection	1	0
Flaviviral infections		
Dengue fever	2	0
Encephalitis Japanese B	1	0
Fungal infections NEC		
Fungal infection	3	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
Fusobacterium infections		
Necrotising ulcerative gingivostomatitis	1	0
Hepatitis virus infections		
Hepatitis A	1	0
Herpes viral infections		
Eczema herpeticum	1	0
Genital herpes	15	0
Herpes ophthalmic	1	0
Herpes simplex	8	0
Herpes simplex reactivation	1	0
Herpes zoster	120	0
Herpes zoster oticus	3	0
Nasal herpes	1	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	93	0
Varicella	3	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	2	0
Abscess limb	2	0
Abscess rupture	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Empyema	1	1
Groin infection	1	0
Infection	90	0
Injection site infection	1	0
Localised infection	19	0
Lymph gland infection	2	0
Lymph node abscess	3	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
Infectious disorders carrier		
SARS-CoV-2 carrier	2	0
Infectious transmissions		
Secondary transmission	2	0
Influenza viral infections		
Influenza	587	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	6	0
Lower respiratory tract infection	70	1
Pleural infection	1	0
Pneumonia	16	1
Pneumonia aspiration	1	0
Male reproductive tract infections		
Epididymitis	1	0
Orchitis	3	0
Mumps viral infections		
Mumps	1	0
Nematode infections		
Enterobiasis	1	0
Orthopox viral infections		
Vaccinia virus infection	1	0
Parvoviral infections		
Erythema infectiosum	1	0
Rabies viral infections		
Rabies	1	1
Rotaviral infections		
Gastroenteritis rotavirus	1	0
Rubella viral infections		
Rubella	2	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Intestinal sepsis	1	0
Sepsis	5	0
Septic shock	1	0
Urosepsis	1	0
Skin structures and soft tissue infections		
Acne pustular	1	0
Blister infected	1	0
Eczema infected	1	0
Impetigo	6	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Infected skin ulcer	1	0
Pustule	11	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	15	0
Vaccination site pustule	1	0
Staphylococcal infections		
Furuncle	10	0
Streptococcal infections		
Pharyngitis streptococcal	1	0
Tinea infections		
Body tinea	3	0
Tinea capitis	1	0
Tinea infection	1	0
Tuberculous infections		
Lymph node tuberculosis	1	0
Upper respiratory tract infections		
Acute sinusitis	2	0
Chronic sinusitis	1	0
Laryngitis	6	0
Nasopharyngitis	306	0
Peritonsillar abscess	1	0
Pharyngitis	6	0
Rhinitis	8	0
Sinusitis	34	0
Tonsillitis	15	0
Upper respiratory tract infection	3	0
Urinary tract infections		
Cystitis	11	0
Kidney infection	5	0
Urinary tract infection	42	0
Vascular infections		
Lymphangitis	3	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	1	0
Gastroenteritis viral	3	0
Meningitis viral	2	0
Pneumonia viral	1	0
Post viral fatigue syndrome	8	0
Sweating fever	59	0
Vestibular neuronitis	4	0
Viral infection	8	0
Viral labyrinthitis	2	0
Viral pharyngitis	6	0
Viral rash	7	0
Infections SOC TOTAL	2295	4

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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	2	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	17	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	24	0
Foetal exposure during pregnancy	10	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	568	0
Maternal exposure during pregnancy	269	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	6	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	8	0
Heat stroke	8	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	8	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	26	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
Wrong technique in product usage process	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	3	0
Ligament sprain	2	0
Muscle injury	5	0
Muscle strain	5	0
Tendon injury	2	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	21	0
Nerve root injury lumbar	1	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	5	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	5	0
Bite	1	0
Electric shock	6	0
Fall	34	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
<i>Non-site specific procedural complications</i>		
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
<i>Occupational exposures</i>		
Occupational exposure to toxic agent	1	0
<i>Off label uses</i>		
Off label use	23	0
<i>Overdoses NEC</i>		
Overdose	6	0
<i>Peripheral nerve injuries</i>		
Sciatic nerve injury	1	0
Ulnar nerve injury	1	0
<i>Poisoning and toxicity</i>		
Systemic toxicity	1	0
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	65	0
Expired product administered	31	0
Extra dose administered	5	0
Inappropriate schedule of product administration	59	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	10	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Incorrect product administration duration	1	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
Wrong product administered	2	0
Product dispensing errors and issues		
Product dispensing error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	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	47	0
Nasal injury	1	0
Skin injuries NEC		
Contusion	336	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
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		
Vaccination complication	15	0
Injuries SOC TOTAL	1819	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Auditory and vestibular diagnostic procedures</i>		
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Rheumatoid factor increased	1	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Campylobacter test positive	1	0
<i>Blood counts NEC</i>		
Full blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	2	0
Oxygen saturation decreased	15	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose decreased	2	0
Blood glucose increased	7	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	4	0
Heart sounds	5	0
<i>Cardiac function diagnostic procedures</i>		
Ejection fraction decreased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Chemistry analyses NEC</i>		
Histamine abnormal	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	1	0
Low density lipoprotein increased	1	0
<i>Coagulation and bleeding analyses</i>		
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	1	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
<i>ECG investigations</i>		
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
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	16	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Fertility analyses</i>		
Semen analysis abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
X-ray with contrast upper gastrointestinal tract	1	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastric pH decreased	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	259	0
Heart rate abnormal	22	0
Heart rate decreased	14	0
Heart rate increased	398	0
Heart rate irregular	77	0
Heart rate variability decreased	1	0
Maximum heart rate	1	0
Maximum heart rate increased	1	0
Pulse abnormal	1	0
Pulse absent	1	0
Sinus rhythm	3	0
<i>Imaging procedures NEC</i>		
X-ray	1	0
<i>Immunology analyses NEC</i>		
Immunology test	1	0
<i>Investigations NEC</i>		
Blood test	1	0
Blood test abnormal	5	0
Blood test normal	1	0
Polymerase chain reaction positive	2	0
<i>Liver function analyses</i>		
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
Transaminases increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood calcium increased	2	0
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	3	0
Blood sodium decreased	1	0
Serum ferritin increased	1	0
Urine copper	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Bone scan	1	0
<i>Musculoskeletal and soft tissue tests NEC</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Tender joint count	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Electromyogram abnormal	1	0
Sensory level	1	0
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	1	0
Visual tracking test	1	0
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	100	0
Body temperature abnormal	11	0
Body temperature decreased	16	0
Body temperature fluctuation	24	0
Body temperature increased	116	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	4	0
Respiratory rate decreased	6	0
Respiratory rate increased	10	0
Skin temperature	23	0
Temperature difference of extremities	5	0
Weight decreased	23	0
Weight increased	10	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
Platelet analyses		
Platelet count decreased	10	0
Protein analyses NEC		
C-reactive protein increased	8	0
Red blood cell analyses		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
Renal function analyses		
Blood creatinine increased	1	0
Reproductive hormone analyses		
Blood testosterone decreased	1	0
False negative pregnancy test	1	0
Pregnancy test	1	0
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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	2	0
Pulmonary function test decreased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
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
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	5	0
<i>Thyroid analyses</i>		
Tri-iodothyronine decreased	1	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
Blood lactate dehydrogenase increased	1	0
<i>Urinalysis NEC</i>		
Blood urine	5	0
Blood urine present	25	0
Protein urine	1	0
pH urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	12	0
Urine output decreased	1	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	2	0
Blood pressure decreased	11	0
Blood pressure diastolic increased	1	0
Blood pressure increased	34	0
Blood pressure measurement	7	0
Blood pressure normal	1	0
<i>Virus identification and serology</i>		
Coronavirus test	4	0
Influenza A virus test	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	7	0
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
Neutrophil count	1	0
Neutrophil count decreased	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	1481	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	419	0
Food craving	2	0
Food refusal	4	0
Hyperphagia	5	0
Hypophagia	2	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	20	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	8	0
Feeding disorder	47	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	9	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	103	0
<i>Total fluid volume increased</i>		
Fluid retention	11	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	695	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	53	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	1	0
Medial tibial stress syndrome	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	106	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	98	0
Pubic pain	1	0
Spinal pain	17	0
<i>Bursal disorders</i>		
Bursitis	24	0
<i>Cartilage disorders</i>		
Costochondritis	22	0
<i>Connective tissue disorders NEC</i>		
Morphoea	1	0
Polymyalgia rheumatica	4	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>		
Hypermobility syndrome	1	0
Joint lock	10	0
Periarthritis	50	0
Rotator cuff syndrome	5	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2500	0
Joint effusion	1	0
Joint noise	3	0
Joint range of motion decreased	1	0
Joint stiffness	71	0
Joint swelling	85	0
Joint vibration	2	0
Joint warmth	7	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Systemic lupus erythematosus	2	0
Muscle infections and inflammations		
Myositis	9	0
Muscle pains		
Fibromyalgia	25	0
Myalgia	3255	0
Myalgia intercostal	1	0
Muscle related signs and symptoms NEC		
Muscle atrophy	2	0
Muscle discomfort	2	0
Muscle fatigue	107	0
Muscle haemorrhage	1	0
Muscle spasms	489	0
Muscle swelling	17	0
Muscle tightness	30	0
Muscle twitching	91	0
Myosclerosis	1	0
Muscle tone abnormalities		
Muscle rigidity	4	0
Nuchal rigidity	5	0
Trismus	9	0
Muscle weakness conditions		
Muscular weakness	227	0
Musculoskeletal and connective tissue conditions NEC		
Growth retardation	1	0
Limb mass	2	0
Mastication disorder	2	0
Mobility decreased	21	0
Muscle contracture	1	0
Musculoskeletal disorder	2	0
Musculoskeletal stiffness	463	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
Musculoskeletal and connective tissue pain and discomfort		
Back pain	805	0
Flank pain	18	0
Limb discomfort	385	0
Musculoskeletal chest pain	65	0
Musculoskeletal discomfort	23	0
Musculoskeletal pain	24	0
Neck pain	475	0
Pain in extremity	3886	1
Sacral pain	1	0
Myopathies		
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	5	0
Psoriatic arthropathies		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Psoriatic arthropathy	3	0
Rheumatoid arthropathies		
Rheumatoid arthritis	17	0
Soft tissue disorders NEC		
Axillary mass	59	0
Fluctuance	1	0
Groin pain	27	0
Neck mass	13	0
Soft tissue swelling	2	0
Spine and neck deformities		
Spinal stenosis	1	0
Spondyloarthropathies		
Ankylosing spondylitis	4	0
Arthritis reactive	18	0
Axial spondyloarthritis	1	0
Spondylitis	1	0
Synovial disorders		
Synovial cyst	5	0
Synovitis	2	0
Tendon disorders		
Tendon pain	4	0
Tendonitis	6	0
Trigger finger	3	0
Trunk deformities		
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	13728	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	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	4	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>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	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	44	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	17	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	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	35	1
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	0
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	3	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	1	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	1	0
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	3	0
Balance disorder	86	0
Coordination abnormal	7	0
Dysstasia	14	0
Nystagmus	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	6	0
Dysgraphia	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	13	0
Lethargy	498	0
Loss of consciousness	263	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Somnolence	266	0
Stupor	1	0
Syncope	1087	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	1	0
Bradykinesia	4	0
Clumsiness	4	0
Dyskinesia	13	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	4	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	57	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	64	0
Cold-stimulus headache	11	0
Drug withdrawal headache	2	0
Headache	8072	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	104	0
Tension headache	168	0
Thunderclap headache	3	0
Vascular headache	7	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<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	52	0
Memory impairment	34	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	22	0
Disturbance in attention	82	0
Mental impairment	14	0
<i>Migraine headaches</i>		
Basilar migraine	1	0
Hemiplegic migraine	6	0
Migraine	828	0
Migraine with aura	48	0
Migraine without aura	3	0
Retinal migraine	4	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	4	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	6	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	4	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	29	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>		
Tunnel vision	13	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	3212	0
Dizziness exertional	11	0
Dizziness postural	215	0
Drooling	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Exaggerated startle response	1	0
Head discomfort	66	0
Meningism	1	0
Neurological symptom	11	0
Persistent postural-perceptual dizziness	3	0
Presyncope	249	0
Tongue biting	2	0
Unresponsive to stimuli	12	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	39	0
Hyposmia	2	0
Parosmia	44	0
Optic nerve disorders NEC		
Optic neuritis	5	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	5	0
Burning sensation	124	0
Dysaesthesia	1	0
Formication	7	0
Hemianaesthesia	2	0
Hyperaesthesia	54	0
Hypoaesthesia	666	0
Paraesthesia	951	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	3	0
Hemiparesis	4	0
Hemiplegia	9	0
Monoparesis	24	0
Monoplegia	27	0
Paralysis	33	0
Paraparesis	2	0
Paresis	2	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	12	0
Reduced facial expression	1	0
Partial complex seizures		
Focal dyscognitive seizures	1	0
Peripheral neuropathies NEC		
Autoimmune neuropathy	2	0
Neuralgic amyotrophy	3	0
Neuritis	2	0
Neuropathy peripheral	14	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	2	0
Seizures and seizure disorders NEC		
Epilepsy	23	0
Febrile convulsion	5	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myoclonic epilepsy	1	0
Partial seizures	7	0
Psychogenic seizure	1	0
Seizure	182	0
Seizure anoxic	1	0
Seizure cluster	1	0
Status epilepticus	28	0
Tonic clonic movements	3	0
Tonic convulsion	5	0
Sensory abnormalities NEC		
Ageusia	87	0
Allodynia	3	0
Aura	3	0
Complex regional pain syndrome	1	0
Dysgeusia	226	0
Electric shock sensation	14	0
Hypogeusia	1	0
Neuralgia	145	0
Post herpetic neuralgia	3	0
Restless legs syndrome	45	0
Sensory disturbance	22	0
Sensory loss	33	0
Taste disorder	51	0
Vibratory sense increased	2	0
Sleep disturbances NEC		
Sleep deficit	5	0
Speech and language abnormalities		
Dysarthria	35	0
Incoherent	10	0
Slow speech	5	0
Speech disorder	15	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	3	0
Radiculopathy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	20	0
Tremor (excl congenital)		
Essential tremor	1	0
Head titubation	2	0
Tremor	664	0
Trigeminal disorders		
Trigeminal neuralgia	6	0
Nervous system disorders SOC TOTAL	19755	4

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	66	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	4	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>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 pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Stillbirth	1	1
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	102	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	1	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	1	0
<i>Product physical issues</i>		
Product after taste	1	0
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
<i>Product supply and availability issues</i>		
Product availability issue	2	0
null SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	6	0
Breath holding	3	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	23	0
Anxiety	257	0
Nervousness	48	0
Stress	21	0
Tension	10	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	4	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Disinhibition	1	0
Homicidal ideation	1	0
Impatience	1	0
Paranoia	6	0
Personality change	2	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	61	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	211	0
Disorientation	89	0
<i>Deliria</i>		
Delirium	51	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	2	0
Delusion of parasitosis	1	0
<i>Depressive disorders</i>		
Depression	94	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	2	0
Dissociation	13	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	7	0
Insomnia	482	0
Middle insomnia	14	0
Terminal insomnia	13	0
<i>Dyssomnias</i>		
Poor quality sleep	93	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	53	0
Mood altered	19	0
<i>Factitious disorders</i>		
Factitious disorder	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	6	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	121	0
Hallucination, auditory	6	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	4	0
Hallucinations, mixed	2	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	95	0
Feeling of despair	5	0
Negative thoughts	1	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	4	0
<i>Mood disorders NEC</i>		
Affective disorder	2	0
Apathy	13	0
Listless	7	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	56	0
Panic reaction	12	0
<i>Paraphilias and paraphilic disorders</i>		
Exhibitionism	1	0
<i>Parasomnias</i>		
Abnormal dreams	39	0
Abnormal sleep-related event	1	0
Nightmare	60	0
Sleep inertia	1	0
Sleep talking	2	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	5	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	2	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	75	0
<i>Somatic symptom disorders</i>		
Conversion disorder	5	0
Habit cough	7	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<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	1	0
Suicidal behaviour	2	0
Suicidal ideation	20	0
Suicide attempt	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	4	0
Intrusive thoughts	1	0
Tachyphrenia	4	0
Thinking abnormal	4	0
Thought blocking	2	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	2438	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	1	0
Bladder pain	10	0
Dysuria	10	0
Incontinence	11	0
Micturition urgency	13	0
Pollakiuria	44	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	13	0
Urinary retention	8	0
Urinary straining	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	2	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	2	0
Loss of bladder sensation	1	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
<i>Urinary abnormalities</i>		
Chromaturia	20	0
Haematuria	9	0
Loin pain haematuria syndrome	1	0
Urine abnormality	5	0
Urine odour abnormal	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	8	0
Nocturia	1	0
Renal pain	107	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	298	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	19	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	148	0
Breast swelling	23	0
Breast tenderness	15	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	4	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	479	0
Intermenstrual bleeding	252	0
Menstrual discomfort	4	0
Menstrual disorder	410	0
Menstruation irregular	682	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	100	0
Hypomenorrhoea	117	0
Menstruation delayed	836	0
Oligomenorrhoea	35	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1062	0
Menometrorrhagia	9	0
Polymenorrhoea	179	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	20	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	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital odour	1	0
Genital pain	2	0
Pelvic discomfort	1	0
Pelvic pain	34	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	4	0
Infertility female	1	0
Sexual dysfunction	2	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0
Testicular mass	1	0
Testicular pain	21	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Testicular swelling	6	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	21	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	16	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	339	0
Vaginal ulceration	3	0
Vulval haemorrhage	10	0
Vulval ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	20	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	5149	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	1570	0
Dyspnoea at rest	1	0
Dyspnoea exertional	7	0
Hyperventilation	15	0
Hypopnoea	31	0
Hypoventilation	1	0
Irregular breathing	6	0
Mouth breathing	1	0
Respiration abnormal	23	0
Respiratory arrest	1	1
Respiratory distress	2	0
Sleep apnoea syndrome	4	0
Tachypnoea	7	0
<i>Bronchospasm and obstruction</i>		
Asthma	77	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	122	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	3	0
Cough	611	0
Haemoptysis	4	0
Productive cough	37	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	1	0
Pleuritic pain	2	0
Pulmonary haemorrhage	1	0
Pulmonary pain	27	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	68	0
Nasal inflammation	1	0
Rhinitis allergic	1	0
<i>Nasal disorders NEC</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Epistaxis	193	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	64	0
Tonsillar erythema	3	0
Tonsillar hypertrophy	15	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	64	1
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	3	0
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	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	19	0
Catarrh	7	0
Choking	6	0
Dry throat	30	0
Dysphonia	24	0
Increased viscosity of upper respiratory secretion	5	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Nasal discomfort	8	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	571	0
Paranasal sinus discomfort	8	0
Rhinalgia	6	0
Rhinorrhoea	170	0
Sinus pain	75	0
Sneezing	58	0
Throat irritation	43	0
Throat tightness	53	0
Upper-airway cough syndrome	5	0
Yawning	9	0
Respiratory disorders SOC TOTAL	4205	2

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	37	0
Acne cystic	2	0
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	66	0
Alopecia areata	16	0
Alopecia totalis	2	0
<i>Angioedemas</i>		
Angioedema	62	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	279	0
Hidradenitis	2	0
Hyperhidrosis	965	0
Miliaria	70	0
Night sweats	310	0
<i>Bullous conditions</i>		
Blister	94	0
Blister rupture	2	0
Blood blister	3	0
Dermatitis bullous	3	0
Erythema multiforme	15	0
Pemphigoid	1	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	103	0
Pain of skin	142	0
Papule	22	0
Scab	5	0
Scar pain	6	0
Sensitive skin	144	0
Skin burning sensation	75	0
Skin discolouration	40	0
Skin discomfort	2	0
Skin disorder	3	0
Skin induration	8	0
Skin lesion	26	0
Skin necrosis	2	0
Skin odour abnormal	3	0
Skin plaque	1	0
Skin reaction	122	0
Skin sensitisation	15	0
Skin swelling	28	0
Skin texture abnormal	1	0
Skin tightness	7	0
Skin warm	236	0
Skin weeping	2	0
Yellow skin	4	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	46	0
Dermatitis allergic	113	0
Dermatitis atopic	18	0
Dermatitis contact	9	0
Dyshidrotic eczema	12	0
Eczema	83	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Flagellate dermatitis	1	0
Hand dermatitis	1	0
Neurodermatitis	1	0
Skin irritation	36	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	4	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	1194	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	3	0
Skin exfoliation	20	0
<i>Hyperpigmentation disorders</i>		
Ephelides	2	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Skin hypopigmentation	1	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	1	0
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	11	0
<i>Papulosquamous conditions</i>		
Lichen planus	5	0
Parapsoriasis	1	0
Pityriasis rosea	17	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	19	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	16	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Trichodynia	1	0
Trichorrhexis	1	0
Pruritus NEC		
Itching scar	4	0
Pruritus	2520	0
Psoriatic conditions		
Guttate psoriasis	2	0
Palmoplantar pustulosis	1	0
Psoriasis	31	0
Rebound psoriasis	1	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Petechiae	22	0
Purpura	12	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	2884	0
Rash erythematous	1090	0
Rash macular	198	0
Rash maculo-papular	6	0
Rash morbilliform	8	0
Rash papular	184	0
Rash pruritic	610	0
Rash vesicular	13	0
Rosaceas		
Rosacea	2	0
Scaly conditions		
Pityriasis	5	0
Sebaceous gland disorders		
Seborrhoea	2	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	4	0
Skin mass	12	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	7	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	3	0
Skin hypoplasias and atrophies		
Skin atrophy	3	0
Skin injuries and mechanical dermatoses		
Needle track marks	2	0
Skin vasculitides		
Cutaneous vasculitis	3	0
Vasculitic rash	2	0
Skin vasomotor conditions		
Livedo reticularis	5	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	4	0
Cold urticaria	1	0
Idiopathic urticaria	5	0
Mechanical urticaria	23	0
Urticaria	693	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	7	0
Urticaria contact	1	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	12964	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	2	0
Menopause	8	0
Postmenopause	2	0
<i>Disability issues</i>		
Bedridden	8	0
Disability	1	0
Immobile	4	0
Impaired driving ability	2	0
Impaired work ability	1	0
Loss of personal independence in daily activities	2	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	44	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	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	19	0
Immunisation	21	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	1	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	24	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	111	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	8	0
Neurogenic shock	1	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Bloody discharge	2	0
Haematoma	7	0
Haemorrhage	233	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	64	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	6	0
Deep vein thrombosis	54	0
Pelvic venous thrombosis	2	0
Superficial vein thrombosis	2	0
Thrombophlebitis	5	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	11	0
Erythromelalgia	1	0
Flushing	58	0
Hot flush	309	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	1	0
Peripheral coldness	108	0
Peripheral ischaemia	1	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Poor peripheral circulation	2	0
Raynaud's phenomenon	9	0
Site specific vascular disorders NEC		
Pallor	86	0
Varicose veins NEC		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	5	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Hypertension	108	0
Prehypertension	1	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	1	0
Hypotension	101	0
Orthostatic hypotension	6	0
Vasculitides NEC		
Vasculitis	6	0
Vena caval embolism and thrombosis		
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1276	0
TOTAL REACTIONS FOR DRUG	122095	43
TOTAL REPORTS	36682	
TOTAL FATAL OUTCOME REPORTS		43