

COVID-19 Moderna vaccine

All UK spontaneous reports received up to and including G21 for COVID-19 Moderna vaccine

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Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine

Report Run Date: 23-Dec-2021

Data Lock Date: 22-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	4	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	4	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	2	0
Hypercoagulation	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Mast cell activation syndrome	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	269	0
Lymph node ulcer	1	0
Lymphadenitis	20	0
Lymphadenopathy	1555	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	2	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	6	0
Thrombocytopenia	24	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	1898	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	2	0
Bundle branch block left	1	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	11	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	1025	0
<i>Cardiomyopathies</i>		
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Coronary artery occlusion	1	0
Coronary artery stenosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	3	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Angina pectoris	40	0
Myocardial infarction	12	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	4	0
Left ventricular dysfunction	2	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
<i>Noninfectious myocarditis</i>		
Hypersensitivity myocarditis	1	0
Myocarditis	131	0
<i>Noninfectious pericarditis</i>		
Pericarditis	73	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	21	0
Bradycardia	10	0
Cardiac fibrillation	1	0
Cardiac flutter	92	0
Extrasystoles	27	0
Tachycardia	374	0
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	22	0
Atrial flutter	9	0
Atrial tachycardia	1	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Sinus arrhythmia	1	0
Sinus tachycardia	6	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	10	2
Ventricular extrasystoles	1	0
Ventricular tachycardia	3	0
Cardiac disorders SOC TOTAL	1908	2

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	3	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Haematological disorders congenital NEC</i>		
Infantile genetic agranulocytosis	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	11	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	7	0
Ear discomfort	6	0
Ear disorder	3	0
Ear inflammation	1	0
Ear pain	216	0
Ear swelling	4	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	30	0
Deafness transitory	1	0
Deafness unilateral	5	0
Hypoacusis	31	0
Sudden hearing loss	10	0
<i>Hyperacusia</i>		
Hyperacusis	6	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	16	0
Tinnitus	289	0
Vertigo	229	0
Vertigo labyrinthine	2	0
Vertigo positional	9	0
Ear disorders SOC TOTAL	872	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	7	0
Ovulation delayed	10	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
Endocrine disorders SOC TOTAL	38	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	2	0
Vitreous detachment	1	0
Vitreous floaters	11	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	7	0
<i>Eyelid movement disorders</i>		
Blepharospasm	26	0
Eyelid ptosis	3	0
<i>Glaucomas (excl congenital)</i>		
Ocular hypertension	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
Uveitis	7	0
<i>Lacrimation disorders</i>		
Dry eye	28	0
Lacrimation increased	11	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Eyelid cyst	1	0
Eyelid irritation	1	0
Eyelid rash	2	0
Swelling of eyelid	19	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	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	3	0
Eye pain	257	0
Eye swelling	93	0
Eyelids pruritus	1	0
Ocular discomfort	6	0
Periorbital oedema	2	0
Periorbital swelling	17	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	3	0
Eye discharge	2	0
Eye inflammation	5	0
Eye irritation	15	0
Eye pruritus	29	0
Ocular hyperaemia	31	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	19	0
Foreign body sensation in eyes	6	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Hypoaesthesia eye	6	0
Photophobia	111	0
Optic disc abnormalities NEC		
Optic discs blurred	1	0
Papilloedema	1	0
Optic nerve bleeding and vascular disorders		
Optic ischaemic neuropathy	1	0
Orbital infections, inflammations and irritations		
Orbital myositis	1	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	2	0
Pupil disorders		
Mydriasis	3	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Astigmatism	3	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	4	0
Retinopathies NEC		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	5	0
Structural change, deposit and degeneration of eye NEC		
Exophthalmos	1	0
Visual colour distortions		
Cyanopsia	1	0
Xanthopsia	1	0
Visual disorders NEC		
Diplopia	24	0
Halo vision	4	0
Metamorphopsia	5	0
Photopsia	23	0
Scintillating scotoma	1	0
Vision blurred	241	0
Visual field disorders		
Visual field defect	4	0
Visual impairment and blindness (excl colour blindness)		
Blindness	20	0
Blindness transient	4	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	43	0
Eye disorders SOC TOTAL	1143	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal pains</i>		
Proctalgia	5	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	3	0
Colitis ulcerative	6	0
Crohn's disease	8	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teething	2	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	4	0
Hyperaesthesia teeth	6	0
Toothache	24	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	885	0
Diarrhoea haemorrhagic	5	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	103	0
Epigastric discomfort	1	0
Eructation	11	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	9	0
Faeces soft	1	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	49	0
Flatulence	28	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	254	0
Abdominal pain lower	21	0
Abdominal pain upper	666	0
Abdominal rigidity	3	0
Abdominal tenderness	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastrointestinal pain	24	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	35	0
Gastric dilatation	2	0
Gastrooesophageal reflux disease	31	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
Gastrointestinal disorder	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	121	0
Anal incontinence	3	0
Breath odour	8	0
Dysphagia	26	0
Odynophagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	6	0
Irritable bowel syndrome	10	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discomfort	2	0
Gingival pain	12	0
Gingival swelling	6	0
Noninfective gingivitis	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	12	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	4	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	13	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	3677	0
Regurgitation	1	0
Retching	21	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Vomiting	1369	0
Vomiting projectile	11	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	1	0
Haematemesis	4	0
Haematochezia	9	0
Melaena	1	0
Upper gastrointestinal haemorrhage	5	0
Oral dryness and saliva altered		
Aptyalism	1	0
Dry mouth	86	0
Lip dry	7	0
Saliva altered	2	0
Salivary hypersecretion	8	0
Oral soft tissue disorders NEC		
Chapped lips	2	0
Cheilitis	2	0
Enlarged uvula	1	0
Lip blister	3	0
Lip disorder	1	0
Oral disorder	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	4	0
Oral blood blister	4	0
Oral soft tissue signs and symptoms		
Coating in mouth	2	0
Hypoaesthesia oral	71	0
Lip discolouration	1	0
Lip pain	6	0
Lip pruritus	2	0
Oral discomfort	8	0
Oral mucosal eruption	2	0
Oral mucosal roughening	1	0
Oral pain	28	0
Oral pruritus	1	0
Paraesthesia oral	109	0
Oral soft tissue swelling and oedema		
Lip swelling	155	0
Mouth swelling	13	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	3	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland pain	3	0
Salivary gland enlargements		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	2	0
Stomatitis and ulceration		
Aphthous ulcer	3	0
Lip ulceration	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Mouth ulceration	72	0
Stomatitis	4	0
Tongue disorders		
Glossitis	6	0
Tongue disorder	6	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
Tongue signs and symptoms		
Glossodynia	25	0
Stiff tongue	1	0
Swollen tongue	70	0
Tongue blistering	2	0
Tongue coated	4	0
Tongue discolouration	3	0
Tongue discomfort	5	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	2	0
Tongue pruritus	1	0
Tongue spasm	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	8308	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	3	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	7	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	2	0
<i>Asthenic conditions</i>		
Asthenia	457	0
Chronic fatigue syndrome	5	0
Decreased activity	1	0
Fatigue	4862	0
Malaise	879	0
Sluggishness	1	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	4	0
Temperature regulation disorder	3	0
<i>Death and sudden death</i>		
Death	11	11
Sudden death	2	2
<i>Febrile disorders</i>		
Pyrexia	5338	1
<i>Feelings and sensations NEC</i>		
Chills	3283	0
Feeling abnormal	376	0
Feeling cold	294	0
Feeling drunk	15	0
Feeling hot	305	0
Feeling jittery	11	0
Feeling of body temperature change	93	0
Hangover	20	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Hunger	16	0
Sensation of blood flow	1	0
Sensation of foreign body	7	0
Temperature intolerance	21	0
Thirst	100	0
Gait disturbances		
Gait disturbance	25	0
Gait inability	11	0
Loss of control of legs	3	0
General signs and symptoms NEC		
Condition aggravated	23	0
Crepitations	1	0
Crying	29	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	5	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	508	0
Induration	10	0
Influenza like illness	636	0
Irritability postvaccinal	1	0
Local reaction	25	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1895	0
Screaming	4	0
Secretion discharge	2	0
Swelling	1042	0
Swelling face	149	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflammations		
Granuloma	1	0
Inflammation	145	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site erythema	3	0
Infusion site mass	1	0
Infusion site pain	5	0
Infusion site pruritus	2	0
Infusion site urticaria	4	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	6	0
Injection site bruising	13	0
Injection site cyst	1	0
Injection site discolouration	1	0

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General disorders General disorders cont'd		
Injection site erythema	181	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	13	0
Injection site irritation	3	0
Injection site joint erythema	4	0
Injection site joint pain	1	0
Injection site mass	189	0
Injection site oedema	3	0
Injection site pain	703	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	110	0
Injection site rash	190	0
Injection site reaction	23	0
Injection site swelling	89	0
Injection site urticaria	53	0
Injection site vesicles	3	0
Injection site warmth	91	0
Interactions		
Alcohol interaction	1	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	6	0
Mass	27	0
Nodule	6	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema mucosal	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	6	0
Localised oedema	6	0
Oedema	9	0
Oedema peripheral	11	0
Pain and discomfort NEC		
Axillary pain	729	0
Chest discomfort	338	0
Chest pain	1100	0
Discomfort	100	0
Facial pain	30	0
Hernia pain	1	0
Inflammatory pain	4	0
Non-cardiac chest pain	2	0
Pain	2117	0
Tenderness	175	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adverse drug reaction	96	0
Adverse event	1	0
Adverse reaction	5	0
Drug ineffective	11	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	6	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	2	0
Ulcers NEC		
Ulcer	4	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	8	0
Vaccination site bruising	22	0
Vaccination site discolouration	2	0
Vaccination site discomfort	8	0
Vaccination site eczema	1	0
Vaccination site erythema	286	0
Vaccination site haemorrhage	3	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	19	0
Vaccination site inflammation	12	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 mass	74	0
Vaccination site movement impairment	15	0
Vaccination site oedema	1	0
Vaccination site pain	319	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	67	0
Vaccination site rash	137	0
Vaccination site reaction	5	0
Vaccination site scar	1	0
Vaccination site swelling	181	0
Vaccination site urticaria	12	0
Vaccination site vesicles	2	0
Vaccination site warmth	130	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	7	0
General disorders SOC TOTAL	28553	15

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>		
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 vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	8	0
<i>Hepatocellular damage and hepatitis NEC</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
Hepatic disorders SOC TOTAL	32	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine

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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	280	0
Infusion related hypersensitivity reaction	12	0
Multiple allergies	3	0
Serum sickness	3	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	10	0
Food allergy	2	0
Milk allergy	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	57	0
Anaphylactic shock	6	0
Anaphylactoid reaction	3	0
<i>Atopic disorders</i>		
Seasonal allergy	16	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	45	0
Immune system disorder	2	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	487	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	6	0
Diverticulitis	3	0
Dysentery	1	0
Gastroenteritis	3	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	69	0
Folliculitis	1	0
Injection site cellulitis	2	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	4	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	5	0
<i>Candida infections</i>		
Candida infection	5	0
Oral candidiasis	2	0
Vulvovaginal candidiasis	7	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Meningitis	2	0
Meningitis aseptic	1	0
<i>Coronavirus infections</i>		
COVID-19	122	0
COVID-19 pneumonia	5	0
Suspected COVID-19	3	0
<i>Coxiella infections</i>		
Q fever	5	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	1	0
Cytomegalovirus infection reactivation	2	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	2	0
Sialoadenitis	1	0
Tooth abscess	1	0
Tooth infection	2	0
<i>Ear infections</i>		
Ear infection	7	0
Labyrinthitis	9	0
Otitis externa	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Conjunctivitis	10	0
Eye infection	2	0
Eyelid boil	1	0
Hordeolum	2	0
Female reproductive tract infections		
Vaginal infection	1	0
Flaviviral infections		
Dengue fever	2	0
Encephalitis Japanese B	1	0
Fungal infections NEC		
Fungal infection	3	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
Fusobacterium infections		
Necrotising ulcerative gingivostomatitis	1	0
Herpes viral infections		
Eczema herpeticum	2	0
Genital herpes	11	0
Herpes ophthalmic	1	0
Herpes simplex	3	0
Herpes zoster	74	0
Herpes zoster oticus	1	0
Nasal herpes	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	74	0
Varicella	3	0
Infections NEC		
Abscess limb	1	0
Abscess rupture	1	0
Infection	77	0
Injection site infection	1	0
Localised infection	18	0
Lymph gland infection	1	0
Lymph node abscess	1	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	4	0
Vestibulitis	1	0
Wound infection	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	2	0
Infectious transmissions		
Secondary transmission	2	0
Influenza viral infections		
Influenza	464	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	4	0
Lower respiratory tract infection	48	1
Pleural infection	1	0
Pneumonia	11	1
Male reproductive tract infections		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Epididymitis	1	0
Orchitis	2	0
Mumps viral infections		
Mumps	1	0
Nematode infections		
Enterobiasis	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	2	0
Septic shock	1	0
Urosepsis	1	0
Skin structures and soft tissue infections		
Acne pustular	1	0
Eczema infected	1	0
Impetigo	3	0
Pustule	9	0
Pyoderma	1	0
Rash pustular	2	0
Skin infection	11	0
Vaccination site pustule	1	0
Staphylococcal infections		
Furuncle	9	0
Streptococcal infections		
Pharyngitis streptococcal	1	0
Tinea infections		
Body tinea	3	0
Tinea infection	1	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
Upper respiratory tract infections		
Acute sinusitis	1	0
Laryngitis	3	0
Nasopharyngitis	258	0
Peritonsillar abscess	1	0
Pharyngitis	4	0
Rhinitis	5	0
Sinusitis	20	0
Tonsillitis	11	0
Upper respiratory tract infection	2	0
Urinary tract infections		
Cystitis	10	0
Kidney infection	3	0
Urinary tract infection	27	0
Vascular infections		
Lymphangitis	2	0
Viral infections NEC		

Case Series Drug Analysis Print
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Reaction Name	Total	Fatal
Infections Infections cont'd		
Conjunctivitis viral	1	0
Gastroenteritis viral	2	0
Meningitis viral	1	0
Post viral fatigue syndrome	5	0
Sweating fever	45	0
Vestibular neuronitis	2	0
Viral infection	5	0
Viral labyrinthitis	2	0
Viral pharyngitis	5	0
Viral rash	7	0
Infections SOC TOTAL	1607	3

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Name: COVID-19 Moderna vaccine

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	6	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	2	0
<i>Conditions caused by cold</i>		
Chillblains	14	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	20	0
Foetal exposure during pregnancy	8	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	446	0
Maternal exposure during pregnancy	210	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	3	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat illness	1	0
Heat oedema	5	0
Heat stroke	7	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	8	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	10	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	3	0
Ligament sprain	2	0
Muscle injury	2	0
Muscle strain	2	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	15	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries		
<i>Injuries cont'd</i>		
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	4	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	4	0
Bite	1	0
Electric shock	5	0
Fall	28	0
Inflammation of wound	2	0
Injury	3	0
Multiple injuries	1	0
Nervous system injury	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	23	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	16	0
<i>Overdoses NEC</i>		
Overdose	6	0
<i>Peripheral nerve injuries</i>		
Sciatic nerve injury	1	0
<i>Poisoning and toxicity</i>		
Systemic toxicity	1	0
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	62	0
Expired product administered	28	0
Extra dose administered	2	0
Inappropriate schedule of product administration	35	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
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Product prescribing errors and issues</i>		
Contraindicated product prescribed	1	0
<i>Radiation injuries</i>		
Sunburn	14	0
<i>Renal and urinary tract injuries NEC</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Bladder injury	1	0
Site specific injuries NEC		
Back injury	1	0
Head injury	8	0
Limb injury	28	0
Skin injuries NEC		
Contusion	270	0
Scar	9	0
Scratch	2	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	12	0
Thermal burns of eye	4	0
Thoracic cage fractures and dislocations		
Sternal fracture	1	0
Vaccination related complications		
Vaccination complication	13	0
Injuries SOC TOTAL	1419	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Campylobacter test positive	1	0
<i>Blood counts NEC</i>		
Full blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen consumption decreased	1	0
Oxygen saturation	2	0
Oxygen saturation decreased	10	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose decreased	1	0
Blood glucose increased	3	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	2	0
Heart sounds	4	0
<i>Cardiac function diagnostic procedures</i>		
Ejection fraction decreased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Cholesterol analyses</i>		
Low density lipoprotein increased	1	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time	1	0
Bleeding time abnormal	1	0
Fibrin D dimer increased	2	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	2	0
Electrocardiogram change	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	11	0
<i>Fertility analyses</i>		
Semen analysis abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
X-ray with contrast upper gastrointestinal tract	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	183	0
Heart rate abnormal	16	0
Heart rate decreased	12	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate increased	293	0
Heart rate irregular	49	0
Heart rate variability decreased	1	0
Maximum heart rate increased	1	0
Investigations NEC		
Blood test abnormal	3	0
Polymerase chain reaction positive	1	0
Liver function analyses		
Alanine aminotransferase increased	5	0
Aspartate aminotransferase	2	0
Bile output	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	7	0
Liver function test increased	1	0
Transaminases increased	1	0
Mineral and electrolyte analyses		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone scan	1	0
Musculoskeletal and soft tissue tests NEC		
Tender joint count	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Sensory level	1	0
Ophthalmic function diagnostic procedures		
Visual tracking test	1	0
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	82	0
Body temperature abnormal	7	0
Body temperature decreased	7	0
Body temperature fluctuation	18	0
Body temperature increased	89	0
Breath sounds	1	0
Grip strength	1	0
Grip strength decreased	2	0
Head lag	3	0
Lymph node palpable	3	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	3	0
Respiratory rate decreased	5	0
Respiratory rate increased	8	0
Skin temperature	20	0
Temperature difference of extremities	4	0
Weight decreased	16	0
Weight increased	9	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Platelet analyses		
Platelet count decreased	8	0
Protein analyses NEC		
C-reactive protein increased	7	0
Red blood cell analyses		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
Renal function analyses		
Blood creatinine increased	1	0
Reproductive hormone analyses		
Pregnancy test	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	3	0
Therapeutic drug monitoring analyses		
Analgesic drug level	5	0
Thyroid analyses		
Tri-iodothyronine decreased	1	0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase increased	1	0
Urinalysis NEC		
Blood urine	5	0
Blood urine present	18	0
Protein urine	1	0
pH urine	1	0
Urinary tract function analyses NEC		
Urine output	7	0
Urine output decreased	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	10	0
Blood pressure diastolic increased	1	0
Blood pressure increased	27	0
Blood pressure measurement	5	0
Blood pressure normal	1	0
Virus identification and serology		
Coronavirus test	4	0
Influenza A virus test	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	5	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	1078	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	323	0
Food craving	2	0
Food refusal	3	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	7	0
Salt craving	1	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	3	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	13	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	2	0
Gluten sensitivity	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Abnormal weight gain	6	0
Feeding disorder	42	0
Food aversion	4	0
Neonatal insufficient breast milk syndrome	3	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	7	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	10	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	78	0
<i>Total fluid volume increased</i>		
Fluid retention	8	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	538	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	39	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	8	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	1	0
<i>Bone disorders NEC</i>		
Bone erosion	1	0
Jaw cyst	1	0
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	75	0
Bone swelling	1	0
Coccydynia	1	0
Pain in jaw	77	0
Spinal pain	13	0
<i>Bursal disorders</i>		
Bursitis	19	0
<i>Cartilage disorders</i>		
Costochondritis	14	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
Reynold's syndrome	2	0
<i>Extremity deformities</i>		
Hand deformity	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
Joint lock	7	0
Periarthritis	31	0
Rotator cuff syndrome	4	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	1925	0
Joint noise	3	0
Joint range of motion decreased	1	0
Joint stiffness	58	0
Joint swelling	58	0
Joint vibration	1	0
Joint warmth	4	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Myositis	6	0
<i>Muscle pains</i>		
Fibromyalgia	17	0
Myalgia	2596	0
<i>Muscle related signs and symptoms NEC</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle atrophy	2	0
Muscle discomfort	2	0
Muscle fatigue	82	0
Muscle haemorrhage	1	0
Muscle spasms	383	0
Muscle swelling	12	0
Muscle tightness	21	0
Muscle twitching	69	0
Myosclerosis	1	0
Muscle tone abnormalities		
Muscle rigidity	3	0
Nuchal rigidity	4	0
Trismus	7	0
Muscle weakness conditions		
Muscular weakness	160	0
Musculoskeletal and connective tissue conditions NEC		
Growth retardation	1	0
Limb mass	1	0
Mastication disorder	2	0
Mobility decreased	13	0
Muscle contracture	1	0
Musculoskeletal disorder	2	0
Musculoskeletal stiffness	369	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	596	0
Flank pain	15	0
Limb discomfort	318	0
Musculoskeletal chest pain	46	0
Musculoskeletal discomfort	14	0
Musculoskeletal pain	16	0
Neck pain	348	0
Pain in extremity	3176	0
Sacral pain	1	0
Myopathies		
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	4	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	8	0
Soft tissue disorders NEC		
Axillary mass	46	0
Groin pain	22	0
Neck mass	10	0
Soft tissue swelling	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	3	0
Arthritis reactive	8	0
Axial spondyloarthritis	1	0
<i>Synovial disorders</i>		
Synovial cyst	5	0
<i>Tendon disorders</i>		
Tendon pain	2	0
Tendonitis	3	0
Trigger finger	3	0
<i>Trunk deformities</i>		
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	10769	0

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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	3	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	8	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	1	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
<i>Skin neoplasms benign</i>		
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>Uterine neoplasms benign</i>		
Uterine leiomyoma	2	0
Neoplasms SOC TOTAL	34	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	3	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	8	0
<i>Autonomic nervous system disorders</i>		
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	2	1
Cerebral infarction	1	0
Cerebrovascular accident	16	1
Haemorrhage intracranial	1	0
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	4	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	3	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	67	0
Coordination abnormal	4	0
Dysstasia	8	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	4	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	10	0
Lethargy	397	0
Loss of consciousness	216	0
Somnolence	207	0
Stupor	1	0
Syncope	913	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	8	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	4	0
Foetal movement disorder	1	0
Hyperkinesia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Hypokinesia	10	0
Motor dysfunction	2	0
Movement disorder	11	0
Psychomotor hyperactivity	1	0
Dystonias		
Dystonia	1	0
Eye movement disorders		
IVth nerve paresis	1	0
Facial cranial nerve disorders		
Bell's palsy	66	0
Facial paralysis	34	0
Facial paresis	9	0
Facial spasm	6	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	3	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cluster headache	47	0
Cold-stimulus headache	9	0
Drug withdrawal headache	2	0
Headache	6327	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	85	0
Tension headache	125	0
Thunderclap headache	2	0
Vascular headache	4	0
Hydrocephalic conditions		
Hydrocephalus	1	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	3	0
Lumbar spinal cord and nerve root disorders		
Sciatica	8	0
Memory loss (excl dementia)		
Amnesia	35	0
Memory impairment	25	0
Transient global amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	15	0
Disturbance in attention	66	0
Mental impairment	12	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	4	0
Migraine	619	0
Migraine with aura	37	0
Migraine without aura	3	0
Retinal migraine	4	0
Typical aura without headache	1	0
Vestibular migraine	2	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	4	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	2	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	1	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	3	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	2	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	20	0
Narcolepsy	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	4	0
Psychomotor skills impaired	1	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	9	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	2634	0
Dizziness exertional	7	0
Dizziness postural	161	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	50	0
Neurological symptom	6	0
Persistent postural-perceptual dizziness	2	0
Presyncope	217	0
Tongue biting	1	0
Unresponsive to stimuli	12	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	2	0
Muscle spasticity	4	0
<i>Olfactory nerve disorders</i>		
Anosmia	31	0
Parosmia	32	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	3	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	4	0
Burning sensation	89	0
Dysaesthesia	1	0
Formication	7	0
Hemianaesthesia	2	0
Hyperaesthesia	43	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hypoaesthesia	512	0
Paraesthesia	734	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	1	0
Hemiparesis	4	0
Hemiplegia	6	0
Monoparesis	15	0
Monoplegia	20	0
Paralysis	23	0
Paresis	2	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	11	0
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	1	0
Neuralgic amyotrophy	2	0
Neuritis	1	0
Neuropathy peripheral	9	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	19	0
Febrile convulsion	4	0
Myoclonic epilepsy	1	0
Partial seizures	6	0
Psychogenic seizure	1	0
Seizure	152	0
Seizure anoxic	1	0
Seizure cluster	1	0
Status epilepticus	27	0
Tonic clonic movements	3	0
Tonic convulsion	4	0
<i>Sensory abnormalities NEC</i>		
Ageusia	68	0
Allodynia	2	0
Aura	1	0
Complex regional pain syndrome	1	0
Dysgeusia	191	0
Electric shock sensation	9	0
Hypogeusia	1	0
Neuralgia	89	0
Post herpetic neuralgia	2	0
Restless legs syndrome	37	0
Sensory disturbance	15	0
Sensory loss	26	0
Taste disorder	40	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	5	0
<i>Speech and language abnormalities</i>		
Dysarthria	27	0
Incoherent	9	0
Slow speech	5	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Speech disorder	11	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
Radiculopathy	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	13	0
<i>Tremor (excl congenital)</i>		
Essential tremor	1	0
Head titubation	2	0
Tremor	510	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	4	0
Nervous system disorders SOC TOTAL	15506	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	45	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	3	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	4	0
<i>Maternal complications of labour NEC</i>		
Uterine atony	1	0
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	3	0
Somatic symptom disorder of pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
Pregnancy conditions SOC TOTAL	74	0

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Device malfunction events NEC</i>		
Thrombosis in device	1	0
Undersensing	1	0
<i>Manufacturing materials issues</i>		
Manufacturing materials issue	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	8	0
Suspected product contamination	1	0
<i>Product 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	22	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
Breath holding	1	0
Staring	1	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Flat affect	4	0
Inappropriate affect	2	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	20	0
Anxiety	205	0
Nervousness	36	0
Stress	19	0
Tension	8	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	4	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Disinhibition	1	0
Paranoia	6	0
Personality change	2	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	38	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	157	0
Disorientation	66	0
<i>Deliria</i>		
Delirium	43	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	3	0
Delusion of parasitosis	1	0
<i>Depressive disorders</i>		
Depression	69	0
Depression suicidal	4	0
Major depression	2	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	12	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	4	0
Insomnia	338	0
Middle insomnia	13	0
Terminal insomnia	12	0
<i>Dyssomnias</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Poor quality sleep	73	0
Eating disorders NEC		
Binge eating	1	0
Emotional and mood disturbances NEC		
Anger	12	0
Emotional disorder	17	0
Emotional distress	9	0
Emotional poverty	1	0
Euphoric mood	11	0
Frustration tolerance decreased	1	0
Irritability	45	0
Mood altered	14	0
Factitious disorders		
Factitious disorder	1	0
Fear symptoms and phobic disorders (incl social phobia)		
Fear	3	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
Fluctuating mood symptoms		
Mood swings	12	0
Hallucinations (excl sleep-related)		
Hallucination	94	0
Hallucination, auditory	4	0
Hallucination, tactile	1	0
Hallucination, visual	3	0
Hallucinations, mixed	1	0
Somatic hallucination	1	0
Increased physical activity levels		
Restlessness	49	0
Mental disorders NEC		
Mental disorder	4	0
Mood alterations with depressive symptoms		
Depressed mood	78	0
Feeling of despair	4	0
Negative thoughts	1	0
Tearfulness	6	0
Mood alterations with manic symptoms		
Mania	4	0
Mood disorders NEC		
Apathy	7	0
Listless	6	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Orgasmic disorders and disturbances		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Panic attack	44	0
Panic reaction	9	0
Parasomnias		
Abnormal dreams	33	0
Abnormal sleep-related event	1	0
Nightmare	41	0
Sleep inertia	1	0
Sleep talking	2	0
Sleep terror	5	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	3	0
Derealisation	2	0
Illusion	1	0
Psychiatric elimination disorders		
Enuresis	12	0
Psychiatric symptoms NEC		
Hypervigilance	1	0
Psychiatric symptom	3	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	2	0
Sexual desire disorders		
Libido decreased	5	0
Libido increased	1	0
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	60	0
Somatic symptom disorders		
Conversion disorder	4	0
Habit cough	5	0
Speech and language usage disturbances		
Disorganised speech	1	0
Speech articulation and rhythm disturbances		
Dysphemia	3	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	2	0
Head banging	4	0
Stress disorders		
Acute stress disorder	1	0
Substance related and addictive disorders		
Alcoholism	1	0
Suicidal and self-injurious behaviour		
Completed suicide	2	0
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	15	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	4	0
Intrusive thoughts	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Tachyphrenia	3	0
Thinking abnormal	4	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	1851	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	1	0
Bladder pain	6	0
Dysuria	8	0
Incontinence	9	0
Micturition urgency	9	0
Pollakiuria	33	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	10	0
Urinary retention	3	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>		
IgA nephropathy	2	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	5	0
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	17	0
Haematuria	4	0
Urine abnormality	5	0
Urine odour abnormal	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	7	0
Renal pain	76	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	214	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	3	0
<i>Breast disorders NEC</i>		
Breast enlargement	3	0
Breast mass	13	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	3	0
<i>Breast signs and symptoms</i>		
Breast discharge	2	0
Breast discomfort	2	0
Breast haemorrhage	1	0
Breast oedema	1	0
Breast pain	113	0
Breast swelling	14	0
Breast tenderness	12	0
Nipple pain	2	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	13	0
Erection increased	1	0
Nocturnal emission	1	0
Organic erectile dysfunction	10	0
Painful ejaculation	1	0
Spontaneous penile erection	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	2	0
Lactation disorder	1	0
Lactation puerperal increased	2	0
Suppressed lactation	8	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	8	0
Premature menopause	3	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	13	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	350	0
Intermenstrual bleeding	186	0
Menstrual discomfort	2	0
Menstrual disorder	297	0
Menstruation irregular	496	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	17	0
Premenstrual syndrome	14	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Withdrawal bleed	2	0
Menstruation with decreased bleeding		
Amenorrhoea	70	0
Hypomenorrhoea	89	0
Menstruation delayed	593	0
Oligomenorrhoea	24	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	808	0
Menometrorrhagia	7	0
Polymenorrhoea	118	0
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	7	0
Polycystic ovaries	7	0
Ovarian and fallopian tube disorders NEC		
Ovulation pain	16	0
Premature ovulation	1	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	15	0
Pelvic haemorrhage	2	0
Penile disorders NEC (excl erection and ejaculation)		
Penile pain	1	0
Penis disorder	3	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	2	0
Prostatic signs, symptoms and disorders NEC		
Prostatic pain	1	0
Reproductive tract disorders NEC (excl neoplasms)		
Genital blister	1	0
Genital haemorrhage	2	0
Genital paraesthesia	1	0
Genital ulceration	1	0
Reproductive tract signs and symptoms NEC		
Genital odour	1	0
Genital pain	2	0
Pelvic pain	22	0
Scrotal disorders NEC		
Scrotal pain	9	0
Varicocele	2	0
Sexual function and fertility disorders NEC		
Infertility	3	0
Sexual dysfunction	1	0
Spermatogenesis and semen disorders		
Haematospermia	1	0
Testicular and epididymal disorders NEC		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	16	0
Testicular swelling	4	0
Uterine disorders NEC		
Adenomyosis	1	0
Endometriosis	13	0
Uterine haemorrhage	9	0
Uterine pain	6	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Uterine neoplasms</i>		
Uterine polyp	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	12	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	253	0
Vaginal ulceration	2	0
Vulval haemorrhage	10	0
Vulval ulceration	1	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	13	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	3778	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	990	0
Dyspnoea at rest	1	0
Dyspnoea exertional	4	0
Hyperventilation	7	0
Hypopnoea	17	0
Hypoventilation	1	0
Irregular breathing	3	0
Mouth breathing	1	0
Respiration abnormal	16	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	3	0
Tachypnoea	5	0
<i>Bronchospasm and obstruction</i>		
Asthma	52	0
Asthma exercise induced	1	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	1	0
Childhood asthma	1	0
Chronic obstructive pulmonary disease	1	0
Obstructive airways disorder	1	0
Wheezing	89	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	2	0
Cough	447	0
Haemoptysis	3	0
Productive cough	28	0
Sputum discoloured	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	5	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	15	0
Lower respiratory tract congestion	1	0
Pulmonary haemorrhage	1	0
Pulmonary pain	20	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	55	0
Rhinitis allergic	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	146	0
Nasal dryness	2	0
Nasal oedema	2	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Nasal pruritus	3	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinonasal obstruction	3	0
Sinus congestion	12	0
Sinus disorder	3	0
Parenchymal lung disorders NEC		
Interstitial lung disease	2	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	4	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	56	0
Tonsillar erythema	2	0
Tonsillar hypertrophy	9	0
Tonsillar inflammation	1	0
Pleural infections and inflammations		
Pleurisy	6	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	3	0
Pulmonary hypertensions		
Pulmonary hypertension	1	0
Pulmonary oedemas		
Pulmonary congestion	2	0
Pulmonary oedema	4	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	29	0
Pulmonary thrombosis	1	0
Respiratory failures (excl neonatal)		
Respiratory failure	1	0
Respiratory signs and symptoms NEC		
Diaphragmalgia	3	0
Painful respiration	3	0
Respiratory symptom	2	0
Use of accessory respiratory muscles	1	0
Respiratory tract disorders NEC		
Allergic respiratory disease	1	0
Respiratory disorder	2	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
Upper respiratory tract signs and symptoms		
Aphonia	15	0
Catarrh	2	0
Choking	4	0
Dry throat	25	0
Dysphonia	17	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	8	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	445	0
Paranasal sinus discomfort	7	0
Rhinalgia	5	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Respiratory disorders cont'd		
Rhinorrhoea	141	0
Sinus pain	58	0
Sneezing	45	0
Throat irritation	31	0
Throat tightness	45	0
Upper-airway cough syndrome	4	0
Yawning	6	0
Respiratory disorders SOC TOTAL	2966	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	30	0
Acne cystic	1	0
<i>Alopecias</i>		
Alopecia	43	0
Alopecia areata	7	0
Alopecia totalis	2	0
<i>Angioedemas</i>		
Angioedema	42	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	225	0
Hidradenitis	1	0
Hyperhidrosis	788	0
Miliaria	60	0
Night sweats	220	0
<i>Bullous conditions</i>		
Blister	57	0
Blister rupture	1	0
Blood blister	3	0
Dermatitis bullous	1	0
Erythema multiforme	11	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	83	0
Pain of skin	106	0
Papule	21	0
Scab	5	0
Scar pain	4	0
Sensitive skin	116	0
Skin burning sensation	56	0
Skin discolouration	29	0
Skin discomfort	1	0
Skin disorder	1	0
Skin induration	8	0
Skin lesion	22	0
Skin necrosis	1	0
Skin odour abnormal	2	0
Skin reaction	105	0
Skin sensitisation	13	0
Skin swelling	22	0
Skin tightness	6	0
Skin warm	211	0
Yellow skin	3	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	32	0
Dermatitis allergic	92	0
Dermatitis atopic	11	0
Dermatitis contact	7	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dyshidrotic eczema	11	0
Eczema	53	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Neurodermatitis	1	0
Skin irritation	27	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	1047	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	14	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	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>		
Onychoclasia	1	0
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Lichen planus	3	0
Pityriasis rosea	9	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	16	0
<i>Pilar disorders NEC</i>		
Hair texture abnormal	1	0
Piloerection	13	0
Trichodynia	1	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	2151	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	2	0
Psoriasis	20	0
<i>Purpura and related conditions</i>		
Petechiae	18	0
Purpura	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	2464	0
Rash erythematous	946	0
Rash macular	166	0
Rash maculo-papular	4	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash morbilliform	7	0
Rash papular	160	0
Rash pruritic	521	0
Rash vesicular	6	0
Rosaceas		
Rosacea	2	0
Scaly conditions		
Pityriasis	2	0
Sebaceous gland disorders		
Seborrhoea	1	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	4	0
Skin mass	11	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	3	0
Skin ulcer	4	0
Skin cysts and polyps		
Dermal cyst	7	0
Skin dystrophies		
Keloid scar	2	0
Skin wrinkling	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	2	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	4	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	1	0
Urticaria	433	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	3	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	10645	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	2	0
Menopause	5	0
<i>Disability issues</i>		
Bedridden	4	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>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	5	0
<i>Social issues NEC</i>		
Social problem	1	0
Social circumstances SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	24	0
Immunisation	34	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>		
Limb immobilisation	1	0
<i>Mastectomies</i>		
Breast conserving surgery	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	3	0
Botulinum toxin injection	1	0
Hospitalisation	4	0
Injection	26	0
Interchange of vaccine products	7	0
Localised alternating hot and cold therapy	2	0
Mass excision	1	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	127	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	2	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	6	0
Neurogenic shock	1	0
Shock	4	0
<i>Haemorrhages NEC</i>		
Bloody discharge	2	0
Haematoma	4	0
Haemorrhage	185	0
Internal haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	22	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Embolism venous	1	0
Thrombosis	32	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	6	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	4	0
Deep vein thrombosis	25	0
Pelvic venous thrombosis	1	0
Superficial vein thrombosis	1	0
Thrombophlebitis	3	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	10	0
Flushing	44	0
Hot flush	251	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	1	0
Peripheral coldness	82	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	6	0
<i>Site specific vascular disorders NEC</i>		
Pallor	78	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	75	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Hypotension	83	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	2	0
Vascular disorders SOC TOTAL	963	0
TOTAL REACTIONS FOR DRUG	94872	24
TOTAL REPORTS	28434	
TOTAL FATAL OUTCOME REPORTS		24