

~~MM~~ COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Data Lock Date: 23-Nov-2022 18:30:06

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All UK spontaneous reports received up to and including 23/11/22 for COVID-19 Vaccine Moderna.

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

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 15-Oct-1958

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	3	0
<i>Anaemias NEC</i>		
Anaemia	22	0
Autoimmune anaemia	1	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	3	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	7	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Abnormal clotting factor	2	0
Antiphospholipid syndrome	4	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	5	0
Mastocytosis	1	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
<i>Leukopenias NEC</i>		
Leukopenia	1	0
Lymphopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	381	0
Lymph node ulcer	1	0
Lymphadenitis	31	0
Lymphadenopathy	2316	0
Lymphatic disorder	1	0
Paratracheal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Pancytopenia	2	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	4	0
<i>Platelet disorders NEC</i>		
Platelet disorder	1	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Spleen disorders</i>		
Splenic infarction	2	0
Splenic vein thrombosis	1	0
<i>Thrombocytopenias</i>		

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Immune thrombocytopenia	12	0
Thrombocytopenia	40	0
Thrombocytopenic purpura	2	0
Blood disorders SOC TOTAL	2862	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	8	0
Atrioventricular block complete	2	1
Bundle branch block	1	0
Bundle branch block left	1	0
Bundle branch block right	3	0
Sinoatrial block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	22	0
Cardiac dysfunction	3	0
Cardiac ventricular thrombosis	1	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	3	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	8	0
Palpitations	2109	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	3	0
Congestive cardiomyopathy	1	0
Restrictive cardiomyopathy	1	0
Stress cardiomyopathy	2	0
Toxic cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	3	1
Coronary artery disease	1	0
Coronary artery occlusion	2	1
Coronary artery stenosis	1	0
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	10	0
Cardiac failure acute	1	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	4	0
Acute myocardial infarction	7	1
Angina pectoris	79	0
Angina unstable	3	0
Myocardial infarction	55	6
Myocardial ischaemia	2	0
Prinzmetal angina	2	0
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	9	0
Left ventricular dilatation	1	0
Left ventricular dysfunction	5	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	2	0

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Cardiac disorders Cardiac disorders cont'd		
Myocardial fibrosis	2	0
Myocardial injury	2	0
Myocardial oedema	2	0
<i>Noninfectious myocarditis</i>		
Hypersensitivity myocarditis	1	0
Myocarditis	221	2
Myopericarditis	30	0
<i>Noninfectious pericarditis</i>		
Pericarditis	149	0
Pleuropericarditis	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	5	0
Pericardial haemorrhage	2	1
Pericardial rub	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	41	0
Bradycardia	21	0
Cardiac fibrillation	1	0
Cardiac flutter	161	0
Extrasystoles	64	0
Heart alternation	1	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	6	0
Sinusoidal foetal heart rate pattern	1	0
Tachyarrhythmia	4	0
Tachycardia	911	1
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0
Atrial fibrillation	90	1
Atrial flutter	15	0
Atrial tachycardia	3	0
Sinus arrhythmia	3	0
Sinus tachycardia	15	0
Supraventricular extrasystoles	4	0
Supraventricular tachycardia	11	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	23	10
Ventricular arrhythmia	1	0
Ventricular extrasystoles	5	0
Ventricular fibrillation	2	0
Ventricular tachycardia	8	0
Cardiac disorders SOC TOTAL	4177	26

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Arterial disorders congenital</i>		
Congenital arterial malformation	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	4	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
Hypermobility syndrome	1	0
<i>Gene mutations and other alterations NEC</i>		
Hereditary angioedema	1	0
<i>Haematological disorders congenital NEC</i>		
Neonatal alloimmune thrombocytopenia	1	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	1	0
<i>Pancreatic disorders congenital</i>		
Pancreas divisum	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	2	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
Congenital disorders SOC TOTAL	20	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	12	0
Ear disorder	6	0
Ear inflammation	1	0
Ear pain	364	0
Ear swelling	9	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	3	0
<i>External ear disorders NEC</i>		
Ear canal stenosis	1	0
Excessive cerumen production	3	0
External ear pain	1	0
Red ear syndrome	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	70	0
Deafness neurosensory	3	0
Deafness transitory	1	0
Deafness unilateral	11	0
Hypoacusis	50	0
Sudden hearing loss	17	0
<i>Hyperacusia</i>		
Hyperacusis	13	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	2	0
Vestibular disorder	1	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	4	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	20	0
Tinnitus	533	0
Vertigo	392	0
Vertigo labyrinthine	4	0
Vertigo positional	23	0
<i>Middle ear disorders NEC</i>		
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	1557	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	2	0
Thyroiditis acute	2	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	6	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	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	2	0
Thyroid pain	3	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	4	0
Hyperthyroidism	7	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	5	0
Endocrine disorders SOC TOTAL	70	0

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Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	5	0
<i>Cataract conditions</i>		
Cataract	3	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Vitreous haemorrhage	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	4	0
Vitreous floaters	24	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	2	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	11	0
<i>Corneal infections, oedemas and inflammations</i>		
Ulcerative keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	41	0
Eyelid ptosis	6	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	43	0
Lacrimation increased	26	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	3	0
Erythema of eyelid	3	0
Eyelid cyst	1	0
Eyelid irritation	2	0
Eyelid oedema	4	0
Eyelid rash	2	0
Swelling of eyelid	38	0
<i>Lid, lash and lacrimal structural disorders</i>		
Lagophthalmos	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	2	0
Eye haemorrhage	6	0
<i>Ocular disorders NEC</i>		
Eye disorder	4	0
Eye oedema	1	0
Eye pain	427	0
Eye swelling	149	0
Eye ulcer	1	0
Eyelid disorder	4	0
Eyelids pruritus	3	0
Ocular discomfort	19	0
Periorbital oedema	3	0
Periorbital swelling	25	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	5	0
Eye discharge	5	0
Eye inflammation	8	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye irritation	25	0
Eye pruritus	48	0
Limbal swelling	1	0
Ocular hyperaemia	63	0
Ocular nerve and muscle disorders		
Eye movement disorder	11	0
Gaze palsy	1	0
Ophthalmoplegia	1	0
Strabismus	1	0
Ocular sensation disorders		
Abnormal sensation in eye	2	0
Asthenopia	34	0
Foreign body sensation in eyes	8	0
Hypoaesthesia eye	6	0
Photophobia	152	0
Optic disc abnormalities NEC		
Optic discs blurred	1	0
Papilloedema	1	0
Optic nerve bleeding and vascular disorders		
Optic ischaemic neuropathy	1	0
Orbital infections, inflammations and irritations		
Orbital myositis	2	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	2	0
Orbital oedema	1	0
Pupil disorders		
Anisocoria	1	0
Mydriasis	5	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Astigmatism	3	0
Myopia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal haemorrhage	2	0
Retinal ischaemia	1	0
Retinal vein occlusion	12	0
Retinal structural change, deposit and degeneration		
Macular degeneration	1	0
Macular hole	1	0
Retinal deposits	1	0
Retinal detachment	1	0
Retinal, choroid and vitreous infections and inflammations		
Retinal oedema	1	0
Retinopathies NEC		
Acute macular neuroretinopathy	1	0
Central serous chorioretinopathy	4	0
Serous retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	6	0
Scleritis	1	0
Scleral structural change, deposit and degeneration		
Scleral disorder	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	2	0
<i>Visual colour distortions</i>		
Cyanopsia	2	0
Xanthopsia	2	0
<i>Visual disorders NEC</i>		
Diplopia	44	0
Halo vision	6	0
Metamorphopsia	5	0
Photopsia	40	0
Scintillating scotoma	1	0
Vision blurred	369	0
Visual brightness	1	0
<i>Visual field disorders</i>		
Visual field defect	5	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	2	0
Blindness	46	0
Blindness transient	9	0
Blindness unilateral	4	0
Night blindness	1	0
Visual acuity reduced	3	0
Visual impairment	92	0
Eye disorders SOC TOTAL	1939	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	2	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	4	0
Pancreatitis acute	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	10	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	2	0
Anal rash	1	0
Anorectal discomfort	2	0
<i>Colitis (excl infective)</i>		
Colitis	7	0
Colitis ischaemic	1	0
Colitis ulcerative	11	0
Crohn's disease	8	0
Inflammatory bowel disease	8	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	2	0
Dental paraesthesia	6	0
Hyperaesthesia teeth	9	0
Toothache	46	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1659	0
Diarrhoea haemorrhagic	8	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	187	0
Epigastric discomfort	5	0
Eructation	25	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faeces discoloured	10	0
Faeces hard	1	0
Faeces soft	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	98	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Flatulence	53	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	12	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	413	0
Abdominal pain lower	30	0
Abdominal pain upper	1140	1
Abdominal rigidity	6	0
Abdominal tenderness	5	0
Gastrointestinal pain	56	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	52	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	44	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	3	0
Functional gastrointestinal disorder	4	0
Gastric disorder	2	0
Gastrointestinal disorder	5	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	5	0
Gastrointestinal motility disorder	2	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	2	0
Gastrointestinal tract irritation	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Barrett's oesophagus	1	0
Hyperchlorhydria	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	222	0
Acute abdomen	1	0
Anal incontinence	6	0
Breath odour	11	0
Dysphagia	44	0
Odynophagia	9	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	12	0
Irritable bowel syndrome	23	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal ulcers and perforation, site unspecified</i>		

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Gastrointestinal disorders		
Stress ulcer	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
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discomfort	2	0
Gingival disorder	3	0
Gingival pain	28	0
Gingival swelling	9	0
Noninfective gingivitis	3	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	14	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	8	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	7	0
Rectal haemorrhage	22	0
Small intestinal haemorrhage	1	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	2	0
Steatorrhoea	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	3	0
Nausea	5726	0
Regurgitation	2	0
Retching	44	0
Vomiting	2332	0
Vomiting projectile	37	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	4	0
Haematemesis	9	0
Haematochezia	18	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
<i>Oesophageal disorders NEC</i>		
Oesophageal disorder	1	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	2	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	2	0
Dry mouth	134	0
Lip dry	11	0
Saliva altered	2	0
Salivary hypersecretion	13	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	3	0
Cheilitis	5	0
Enlarged uvula	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip blister	6	0
Lip disorder	1	0
Oral disorder	4	0
Oral lichen planus	1	0
Uvulitis	1	0
Oral soft tissue haemorrhages		
Lip haemorrhage	1	0
Mouth haemorrhage	7	0
Oral blood blister	4	0
Oral soft tissue infections		
Angular cheilitis	1	0
Oral soft tissue signs and symptoms		
Coating in mouth	2	0
Hypoaesthesia oral	101	0
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	13	0
Lip pruritus	3	0
Oral discomfort	16	0
Oral mucosal blistering	3	0
Oral mucosal eruption	3	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	44	0
Oral pruritus	3	0
Paraesthesia oral	161	0
Oral soft tissue swelling and oedema		
Lip oedema	2	0
Lip swelling	267	0
Mouth swelling	28	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	4	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Retroperitoneal fibrosis	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	8	0
Lip ulceration	5	0
Mouth ulceration	119	0
Oral mucosa erosion	1	0
Stomatitis	8	0
Tongue disorders		

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Glossitis	9	0
Tongue disorder	12	0
Tongue haemorrhage	1	0
Tongue ulceration	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	42	0
Stiff tongue	1	0
Swollen tongue	107	0
Tongue blistering	3	0
Tongue coated	5	0
Tongue discolouration	3	0
Tongue discomfort	10	0
Tongue dry	5	0
Tongue eruption	2	0
Tongue exfoliation	1	0
Tongue movement disturbance	1	0
Tongue oedema	4	0
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	1	0
<i>Tooth missing</i>		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	13828	1

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	4	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	2	0
<i>Application and instillation site reactions</i>		
Application site bruise	2	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	5	0
Application site pruritus	10	0
Application site rash	1	0
Application site reaction	1	0
Application site swelling	3	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	5	0
<i>Asthenic conditions</i>		
Asthenia	813	1
Chronic fatigue syndrome	10	0
Decreased activity	1	0
Fatigue	8017	0
Malaise	1467	0
Sluggishness	3	0
<i>Body temperature altered</i>		
Hyperthermia	4	0
Hypothermia	8	0
Temperature regulation disorder	3	0
<i>Complications associated with device NEC</i>		
Complication associated with device	1	0
Injury associated with device	1	0
<i>Death and sudden death</i>		
Cardiac death	2	2
Death	45	44
Sudden cardiac death	1	1
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	7994	1
<i>Feelings and sensations NEC</i>		
Chills	4985	0
Feeling abnormal	570	0
Feeling cold	559	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Feeling drunk	20	0
Feeling hot	424	0
Feeling jittery	16	0
Feeling of body temperature change	155	0
Hangover	23	0
Hunger	19	0
Sensation of blood flow	2	0
Sensation of foreign body	10	0
Temperature intolerance	23	0
Thirst	143	0
Thirst decreased	1	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	76	0
Gait inability	40	0
Loss of control of legs	8	0
General signs and symptoms NEC		
Condition aggravated	60	0
Crepitations	1	0
Crying	44	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	20	0
Fat tissue increased	1	0
Foaming at mouth	2	0
General physical health deterioration	4	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	901	0
Induration	11	0
Influenza like illness	976	0
Irritability postvaccinal	1	0
Local reaction	33	0
Moaning	2	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2478	0
Pre-existing disease	1	0
Screaming	10	0
Secretion discharge	3	0
Swelling	1384	0
Swelling face	253	0
Unevaluable event	1	0
Healing abnormal NEC		
Impaired healing	1	0
Implant and catheter site reactions		
Catheter site related reaction	1	0
Implant site warmth	3	0
Inflammations		
Granuloma	1	0
Inflammation	239	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Scar inflammation	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	2	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	5	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	10	0
Injection site bruising	16	0
Injection site cyst	1	0
Injection site dermatitis	1	0
Injection site discolouration	1	0
Injection site erythema	246	0
Injection site haemorrhage	4	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	21	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	4	0
Injection site mass	236	0
Injection site movement impairment	1	0
Injection site muscle atrophy	1	0
Injection site muscle weakness	1	0
Injection site nodule	2	0
Injection site oedema	6	0
Injection site pain	1042	0
Injection site paraesthesia	2	0
Injection site plaque	1	0
Injection site pruritus	158	0
Injection site rash	224	0
Injection site reaction	28	0
Injection site swelling	134	0
Injection site urticaria	61	0
Injection site vesicles	3	0
Injection site warmth	114	0
Interactions		
Alcohol interaction	2	0
Drug interaction	6	0
Drug-device interaction	2	0
Potentiating drug interaction	1	0
Mass conditions NEC		
Cyst	11	0
Mass	32	0
Nodule	7	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	2	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Mucosal inflammation	3	0
Mucosal pain	1	0
Oedema mucosal	1	0
Polyp	2	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	12	0
Localised oedema	8	0
Oedema	24	0
Oedema peripheral	18	0
Pain and discomfort NEC		
Axillary pain	992	0
Chest discomfort	535	0
Chest pain	2143	0
Discomfort	149	0
Facial discomfort	3	0
Facial pain	53	0
First bite syndrome	1	0
Hernia pain	1	0
Inflammatory pain	6	0
Non-cardiac chest pain	3	0
Pain	3157	0
Tenderness	238	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	558	0
Adverse reaction	6	0
Drug ineffective	38	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	1	0
Therapeutic response changed	1	0
Therapeutic response unexpected	4	0
Treatment failure	1	0
Vaccination failure	20	0
Ulcers NEC		
Ulcer	6	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	21	0
Vaccination site bruising	33	0
Vaccination site discolouration	2	0
Vaccination site discomfort	10	0
Vaccination site eczema	1	0
Vaccination site erythema	327	0
Vaccination site haemorrhage	7	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	23	0
Vaccination site inflammation	24	0
Vaccination site irritation	3	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
 Earliest Reaction Date: 15-Oct-1958

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 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	4	0
Vaccination site joint pain	8	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	4	0
Vaccination site macule	1	0
Vaccination site mass	98	0
Vaccination site movement impairment	28	0
Vaccination site oedema	1	0
Vaccination site pain	497	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	84	0
Vaccination site rash	158	0
Vaccination site reaction	9	0
Vaccination site scar	1	0
Vaccination site swelling	237	0
Vaccination site urticaria	15	0
Vaccination site vesicles	6	0
Vaccination site warmth	160	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Rebound effect	1	0
Withdrawal syndrome	8	0
General disorders SOC TOTAL	44166	51

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
 Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 23-Nov-2022 18:30:06
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	7	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	2	0
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Jaundice	10	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	4	0
Hypertransaminasaemia	2	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Acute on chronic liver failure	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	14	0
Liver tenderness	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	3	0
Drug-induced liver injury	2	0
Hepatic steatosis	1	0
Hepatitis	3	0
Immune-mediated hepatitis	1	0
Liver injury	5	0
Hepatic disorders SOC TOTAL	65	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	3	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	394	0
Infusion related hypersensitivity reaction	15	0
Multiple allergies	4	0
Serum sickness	3	0
Serum sickness-like reaction	2	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	13	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	2	0
Allergy to vaccine	18	0
Drug hypersensitivity	16	0
Food allergy	6	0
Milk allergy	1	0
Perfume sensitivity	2	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	82	0
Anaphylactic shock	9	0
Anaphylactoid reaction	11	0
<i>Atopic disorders</i>		
Seasonal allergy	18	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	4	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	55	0
Immune system disorder	9	0
Immune-mediated adverse reaction	1	0
Immunisation reaction	47	0
Sensitisation	5	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	2	0
Immunosuppression	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	2	0
Immune system disorders SOC TOTAL	738	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	12	0
Appendicitis perforated	1	0
Diverticulitis	6	0
Dysentery	1	0
Gastroenteritis	9	0
Peritonitis	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Arthritis bacterial	1	0
Bacterial infection	3	0
Bacterial vaginosis	1	0
Cellulitis	95	0
Folliculitis	1	0
Injection site cellulitis	2	0
Meningitis bacterial	1	0
Paronychia	1	0
Skin bacterial infection	1	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	4	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
Osteomyelitis	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	2	0
Mastitis	15	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	11	0
Oral candidiasis	8	0
Skin candida	1	0
Vulvovaginal candidiasis	13	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Encephalitis	5	0
Meningitis	6	0
Meningitis aseptic	1	0
Myelitis	1	0
<i>Chlamydial infections</i>		
Eye infection chlamydial	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	2	0
COVID-19	598	0
COVID-19 pneumonia	6	0
Coronavirus infection	1	0
Post-acute COVID-19 syndrome	9	0
Suspected COVID-19	10	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Coxiella infections</i>		
Q fever	11	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>		
Abscess oral	1	0
Gingivitis	2	0
Oral infection	1	0
Sialoadenitis	2	0
Tooth abscess	3	0
Tooth infection	2	0
<i>Ear infections</i>		
Ear infection	12	0
Labyrinthitis	20	0
Otitis externa	1	0
Otosalpingitis	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
Lice infestation	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	4	0
<i>Eye and eyelid infections</i>		
Chorioretinitis	1	0
Conjunctivitis	17	0
Eye infection	5	0
Eyelid boil	1	0
Eyelid infection	1	0
Hordeolum	6	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0
<i>Flaviviral infections</i>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<i>Fungal infections NEC</i>		
Fungal infection	4	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
Vulvovaginal mycotic infection	1	0
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Helicobacter infections</i>		
Helicobacter infection	2	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
<i>Hepatobiliary and spleen infections</i>		
Cholecystitis infective	1	0
<i>Herpes viral infections</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Eczema herpeticum	1	0
Genital herpes	17	0
Herpes ophthalmic	3	0
Herpes simplex	9	0
Herpes simplex reactivation	1	0
Herpes virus infection	1	0
Herpes zoster	200	0
Herpes zoster oticus	4	0
Nasal herpes	1	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	120	0
Varicella	3	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	2	0
Abscess limb	2	0
Abscess rupture	1	0
Empyema	1	1
Groin infection	1	0
Infection	103	0
Injection site infection	1	0
Localised infection	21	0
Lymph gland infection	2	0
Lymph node abscess	3	0
Respiratory tract infection	2	0
Systemic 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	743	0
Leprous infections		
Type 2 lepra reaction	1	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	9	0
Lower respiratory tract infection	100	1
Pleural infection	1	0
Pneumonia	30	6
Pneumonia aspiration	3	1
Male reproductive tract infections		
Epididymitis	3	0
Orchitis	4	0
Mumps viral infections		
Mumps	1	0
Neisseria infections		

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Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Pericarditis gonococcal	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	10	0
Septic shock	1	0
Urosepsis	1	0
Skin structures and soft tissue infections		
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	1	0
Eczema infected	1	0
Impetigo	6	0
Infected skin ulcer	1	0
Nail infection	1	0
Pustule	11	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	16	0
Vaccination site pustule	1	0
Staphylococcal infections		
Furuncle	13	0
Streptococcal infections		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	2	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	3	0
Tinea capitis	1	0
Tinea infection	1	0
Trypanosomal infections		
African trypanosomiasis	1	0
Tuberculous infections		
Lymph node tuberculosis	1	0
Upper respiratory tract infections		
Acute sinusitis	2	0
Chronic sinusitis	1	0
Laryngitis	7	0
Nasopharyngitis	378	0
Peritonsillar abscess	1	0
Pharyngitis	8	0
Rhinitis	9	0

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Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Sinusitis	45	0
Tonsillitis	18	0
Upper respiratory tract infection	3	0
<i>Urinary tract infections</i>		
Cystitis	19	0
Kidney infection	7	0
Pyelonephritis	1	0
Urinary tract infection	51	0
<i>Vascular infections</i>		
Lymphangitis	3	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Gastroenteritis viral	12	0
Meningitis viral	2	0
Pneumonia viral	2	0
Post viral fatigue syndrome	12	0
Sweating fever	81	0
Urinary tract infection viral	1	0
Vestibular neuronitis	4	0
Viral diarrhoea	1	0
Viral infection	11	0
Viral labyrinthitis	2	0
Viral myocarditis	1	0
Viral pharyngitis	7	0
Viral rash	7	0
Infections SOC TOTAL	3160	10

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	4	0
Palate injury	1	0
Tooth 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	4	0
<i>Cardiovascular injuries</i>		
Vascular injury	2	0
<i>Cerebral injuries NEC</i>		
Brain contusion	1	0
Brain herniation	1	0
Concussion	8	0
Subdural haematoma	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	4	0
<i>Conditions caused by cold</i>		
Chillblains	19	0
Cold shock response	2	0
<i>Cranial nerve injuries</i>		
Cranial nerve injury	1	0
Optic nerve injury	1	0
<i>Ear injuries NEC</i>		
Deafness traumatic	1	0
Ear canal injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	26	0
Foetal exposure during pregnancy	12	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	629	0
Maternal exposure during pregnancy	298	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	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	8	0
<i>Fractures and dislocations NEC</i>		
Compression fracture	1	0
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	2	0
Procedural vomiting	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	1	0
Heat illness	1	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
Earliest Reaction Date: 15-Oct-1958

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Heat oedema	9	0
Heat stroke	9	0
Limb fractures and dislocations		
Clavicle fracture	8	0
Upper limb fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	6	0
Medication error	126	0
Product use complaint	1	0
Vaccination error	1	0
Wrong schedule	1	0
Wrong technique in device usage process	2	0
Wrong technique in product usage process	3	0
Muscle, tendon and ligament injuries		
Epicondylitis	4	0
Ligament sprain	4	0
Muscle injury	10	0
Muscle rupture	2	0
Muscle strain	6	0
Post-traumatic neck syndrome	1	0
Tendon injury	3	0
Tendon rupture	1	0
Nerve injuries NEC		
Nerve injury	25	0
Nerve root injury lumbar	1	0
Neurological and psychiatric procedural complications		
Procedural dizziness	7	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Arthropod bite	5	0
Bite	1	0
Electric shock	8	0
Fall	82	0
Inflammation of wound	3	0
Injury	5	0
Multiple injuries	1	0
Nervous system injury	1	0
Product package associated injury	1	0
Stab wound	1	0
Struck by lightning	1	0
Wound complication	8	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Non-site specific procedural complications		
Incision site pain	1	0
Infusion related reaction	2	0
Injection related reaction	61	0
Post procedural complication	1	0
Post procedural erythema	1	0
Procedural pain	1	0
Occupational exposures		
Occupational exposure to toxic agent	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Off label uses		
Off label use	39	0
Overdoses NEC		
Overdose	7	0
Peripheral nerve injuries		
Sciatic nerve injury	1	0
Ulnar nerve injury	1	0
Poisoning and toxicity		
Systemic toxicity	1	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	73	0
Accidental underdose	3	0
Expired product administered	88	0
Extra dose administered	92	0
Inappropriate schedule of product administration	105	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	15	0
Incorrect product administration duration	1	0
Incorrect route of product administration	4	0
Poor quality product administered	2	0
Product administered at inappropriate site	10	0
Product administered to patient of inappropriate age	1	0
Product administration error	2	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	3	0
Product confusion errors and issues		
Product label confusion	12	0
Product dispensing errors and issues		
Product dispensing error	1	0
Product monitoring errors and issues		
Product monitoring error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	1	0
Product selection errors and issues		
Product selection error	7	0
Product storage errors and issues in the product use system		
Product storage error	11	0
Product transcribing errors and communication issues		
Product communication issue	1	0
Radiation injuries		
Sunburn	16	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Respiratory tract and thoracic cavity procedural complications		
Post procedural pulmonary embolism	1	0
Site specific injuries NEC		
Back injury	2	0
Head injury	11	0
Limb crushing injury	1	0
Limb injury	65	0
Nasal injury	2	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Skin injuries NEC</i>		
Contusion	401	0
Scar	13	0
Scratch	3	0
Skin abrasion	1	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	4	0
Subcutaneous haematoma	2	0
<i>Skin procedural complications</i>		
Dermal filler reaction	1	0
<i>Skull fractures, facial bone fractures and dislocations</i>		
Jaw fracture	1	0
<i>Spinal cord injuries NEC</i>		
Spinal cord injury cervical	1	0
<i>Stoma complications</i>		
Stoma site discomfort	1	0
Stoma site oedema	1	0
<i>Thermal burns</i>		
Burn oesophageal	1	0
Burns second degree	1	0
Cold burn	1	0
Thermal burn	14	0
Thermal burns of eye	7	0
<i>Thoracic cage fractures and dislocations</i>		
Sternal fracture	1	0
<i>Vaccination related complications</i>		
Adverse event following immunisation	1	0
Vaccination complication	6	0
Injuries SOC TOTAL	2521	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	4	0
Oxygen saturation decreased	26	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose abnormal	3	0
Blood glucose decreased	4	0
Blood glucose increased	10	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	4	0
Heart sounds	7	0
Heart sounds abnormal	1	0
<i>Cardiac function diagnostic procedures</i>		
Ejection fraction decreased	1	0
<i>Cell marker analyses</i>		
Prostatic specific antigen decreased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	2	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF pressure	1	0
<i>Chemistry analyses NEC</i>		
Histamine abnormal	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	2	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	6	0
Fibrin degradation products increased	1	0
International normalised ratio decreased	2	0
International normalised ratio increased	3	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
<i>ECG investigations</i>		
Electrocardiogram	2	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Electrocardiogram ST segment elevation	2	0
Electrocardiogram ST-T segment abnormal	3	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	5	0
Electrocardiogram change	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	16	0
Faecal analyses NEC		
Faecal volume	1	0
Fertility analyses		
Semen analysis abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
Fungus identification and serology		
Fungal test	1	0
Gastrointestinal and abdominal imaging procedures		
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH	1	0
Gastric pH decreased	1	0
Swallow study	1	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin abnormal	1	0
Haematological analyses NEC		
Blood viscosity increased	1	0
Red blood cell sedimentation rate increased	1	0
Heart rate and pulse investigations		
Heart rate	327	0
Heart rate abnormal	29	0
Heart rate decreased	21	0
Heart rate increased	485	0
Heart rate irregular	113	0
Heart rate variability decreased	1	0
Maximum heart rate	1	0
Maximum heart rate increased	1	0
Pulse abnormal	3	0
Pulse absent	1	0
Sinus rhythm	3	0
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	6	0
Aspartate aminotransferase	2	0
Bile output	4	0
Blood bilirubin increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	8	0
Liver function test increased	1	0
Imaging procedures NEC		
X-ray	1	0
Immunology analyses NEC		
Antibody test negative	1	0
Immunology test	1	0
Immunology skin tests NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Allergy alert test	1	0
Allergy alert test positive	1	0
Investigations NEC		
Blood test	1	0
Blood test abnormal	5	0
Blood test normal	2	0
Polymerase chain reaction positive	2	0
Mineral and electrolyte analyses		
Blood calcium decreased	1	0
Blood calcium increased	2	0
Blood iron	1	0
Blood iron decreased	3	0
Blood magnesium decreased	1	0
Blood potassium decreased	3	0
Blood sodium decreased	1	0
Serum ferritin increased	3	0
Urine copper	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone scan	1	0
Face and mouth X-ray abnormal	1	0
X-ray limb normal	1	0
Musculoskeletal and soft tissue tests NEC		
Tender joint count	1	0
Tender joint count increased	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Electromyogram abnormal	1	0
Romberg test positive	1	0
Sensory level	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	2	0
Visual tracking test	1	0
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	135	0
Body temperature abnormal	15	0
Body temperature decreased	21	0
Body temperature fluctuation	35	0
Body temperature increased	174	0
Breath sounds	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	1	0
Grip strength decreased	4	0
Head lag	4	0
Lymph node palpable	5	0
Muscle strength abnormal	4	0
Ophthalmological examination	1	0
Pain assessment	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	6	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Respiratory rate decreased	6	0
Respiratory rate increased	13	0
Skin temperature	30	0
Temperature difference of extremities	6	0
Weight decreased	38	0
Weight increased	13	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	15	0
Platelet count increased	1	0
Platelet count normal	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	13	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	3	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
Blood urea	1	0
Blood urea increased	1	0
Glomerular filtration rate abnormal	1	0
<i>Reproductive hormone analyses</i>		
Blood testosterone decreased	1	0
False negative pregnancy test	2	0
Pregnancy test	1	0
Pregnancy test false positive	1	0
<i>Reproductive organ and breast histopathology procedures</i>		
Smear cervix	1	0
<i>Reproductive organ and breast imaging procedures</i>		
Hysteroscopy	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume	1	0
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	3	0
Maximal voluntary ventilation	1	0
Pulmonary function test decreased	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	2	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin abnormal	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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood lactate dehydrogenase increased	1	0
Phospholipase A2 activity increased	1	0
Urinalysis NEC		
Blood urine	8	0
Blood urine present	31	0
Protein urine	1	0
pH urine	1	0
Urinary tract function analyses NEC		
Urine output	13	0
Urine output decreased	3	0
Urinary tract imaging procedures		
Bladder scan	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	4	0
Blood pressure decreased	15	0
Blood pressure diastolic increased	1	0
Blood pressure increased	64	0
Blood pressure measurement	12	0
Blood pressure normal	1	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	5	0
Influenza A virus test	1	0
Respiratory syncytial virus test positive	1	0
SARS-CoV-2 RNA	2	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	5	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	9	0
Vitamin analyses		
Blood folate decreased	1	0
Vitamin D decreased	1	0
White blood cell analyses		
Neutrophil count	1	0
Neutrophil count decreased	2	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	3	0
Investigations SOC TOTAL	1986	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	3	0
Decreased appetite	564	0
Eating disorder symptom	1	0
Food craving	2	0
Food refusal	7	0
Hyperphagia	5	0
Hypophagia	4	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	7	0
Diabetes mellitus inadequate control	4	0
Type 1 diabetes mellitus	2	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Disorders of purine metabolism</i>		
Gout	30	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	2	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	2	0
Food intolerance	3	0
Gluten sensitivity	1	0
Histamine intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	7	0
Abnormal weight gain	9	0
Feeding disorder	73	0
Food aversion	6	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	13	0
Insulin resistance	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	15	0
<i>Iron excess</i>		
Haemochromatosis	1	0
<i>Magnesium metabolism disorders</i>		
Hypomagnesaemia	1	0
<i>Phosphorus metabolism disorders</i>		
Hypophosphataemia	1	0
<i>Potassium imbalance</i>		

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hypokalaemia	3	0
Sodium imbalance		
Hyponatraemia	3	0
Hyponatraemic syndrome	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	3	0
Total fluid volume decreased		
Dehydration	121	0
Total fluid volume increased		
Fluid retention	13	0
Water soluble vitamin deficiencies		
Folate deficiency	2	0
Metabolic disorders SOC TOTAL	937	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	85	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	11	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	3	0
Rheumatic fever	1	0
<i>Bone disorders NEC</i>		
Bone erosion	1	0
Exostosis	2	0
Jaw cyst	1	0
Jaw disorder	2	0
Medial tibial stress syndrome	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	150	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	119	0
Pubic pain	1	0
Spinal pain	28	0
<i>Bursal disorders</i>		
Bursitis	27	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	28	0
<i>Connective tissue disorders NEC</i>		
Morphoea	1	0
Polymyalgia rheumatica	12	0
Reynold's syndrome	2	0
Systemic scleroderma	2	0
<i>Extremity deformities</i>		
Finger deformity	2	0
Foot deformity	3	0
Hand deformity	2	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	3	0
<i>Joint related disorders NEC</i>		
Greater trochanteric pain syndrome	1	0
Joint lock	13	0
Periarthritis	71	0
Rotator cuff syndrome	11	0
Temporomandibular joint syndrome	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	3237	0
Joint effusion	2	0
Joint noise	5	0
Joint range of motion decreased	1	0
Joint stiffness	109	0
Joint swelling	117	0
Joint vibration	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Joint warmth	8	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	2	0
Systemic lupus erythematosus	4	0
Muscle infections and inflammations		
Myositis	11	0
Muscle pains		
Fibromyalgia	31	0
Myalgia	3977	0
Myalgia intercostal	1	0
Muscle related signs and symptoms NEC		
Muscle atrophy	4	0
Muscle discomfort	3	0
Muscle disorder	3	0
Muscle fatigue	138	0
Muscle haemorrhage	1	0
Muscle mass	1	0
Muscle spasms	573	0
Muscle swelling	19	0
Muscle tightness	36	0
Muscle twitching	104	0
Myosclerosis	1	0
Muscle tone abnormalities		
Muscle rigidity	9	0
Nuchal rigidity	5	0
Trismus	12	0
Muscle weakness conditions		
Muscular weakness	346	0
Musculoskeletal and connective tissue conditions NEC		
Dupuytren's contracture	1	0
Growth retardation	1	0
Limb mass	3	0
Mastication disorder	2	0
Mobility decreased	55	0
Muscle contracture	1	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	580	0
Weight bearing difficulty	2	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dactylitis	1	0
Fasciitis	1	0
Plantar fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	993	0
Flank pain	19	0
Limb discomfort	448	0
Musculoskeletal chest pain	81	0
Musculoskeletal discomfort	33	0
Musculoskeletal pain	29	0
Neck pain	608	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Pain in extremity	4630	1
Sacral pain	1	0
Myopathies		
Myopathy	1	0
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	9	0
Psoriatic arthropathies		
Psoriatic arthropathy	5	0
Rheumatoid arthropathies		
Rheumatoid arthritis	28	0
Soft tissue disorders NEC		
Axillary mass	63	0
Fluctuance	1	0
Groin pain	31	0
Neck mass	15	0
Soft tissue swelling	2	0
Spine and neck deformities		
Cervical spinal stenosis	1	0
Lumbar spinal stenosis	1	0
Scoliosis	1	0
Spondyloarthropathies		
Ankylosing spondylitis	5	0
Arthritis reactive	23	0
Axial spondyloarthritis	1	0
Spondylitis	1	0
Synovial disorders		
Synovial cyst	5	0
Synovitis	3	0
Tendon disorders		
Tendon calcification	1	0
Tendon pain	5	0
Tendonitis	12	0
Trigger finger	3	0
Trunk deformities		
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	17072	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage II	1	0
B-cell lymphoma stage III	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	2	0
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	4	0
<i>Breast neoplasms unspecified malignancy</i>		
Phyllodes tumour	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	1	1
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	10	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>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	1	1
<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	6	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Keratoacanthoma	1	0
Skin cancer	1	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
Small intestine carcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Elastofibroma	2	0
Lipoma	2	0
<i>Soft tissue neoplasms malignant and unspecified NEC (excl sarcomas)</i>		
Solitary fibrous tumour	1	0
<i>Urinary tract neoplasms unspecified malignancy NEC</i>		
Renal neoplasm	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	3	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	1	0
Neoplasms SOC TOTAL	61	2

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Report Run Date: 24-Nov-2022
Earliest Reaction Date: 15-Oct-1958

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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	3	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	31	1
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	3	0
Orthostatic intolerance	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebellar stroke	1	0
Cerebral artery embolism	2	0
Cerebral haemorrhage	7	2
Cerebral infarction	2	0
Cerebral ischaemia	1	0
Cerebrovascular accident	67	3
Haemorrhage intracranial	2	0
Haemorrhagic stroke	2	1
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	9	0
Lacunar infarction	1	0
Lacunar stroke	1	0
Ruptured cerebral aneurysm	1	1
Subarachnoid haemorrhage	9	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	2	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	5	0
Cerebral venous thrombosis	1	0
Superior sagittal sinus thrombosis	2	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervical radiculopathy	3	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	3	0
Demyelinating polyneuropathy	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	7	0
Balance disorder	170	0
Coordination abnormal	12	0
Dysstasia	35	0
Nystagmus	5	0
<i>Cortical dysfunction NEC</i>		
Aphasia	15	0
Dysgraphia	1	0
Dyspraxia	1	0

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Report Run Date: 24-Nov-2022

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	4	0
<i>Demyelinating disorders NEC</i>		
Demyelination	2	0
<i>Disturbances in consciousness NEC</i>		
Consciousness fluctuating	1	0
Depressed level of consciousness	18	0
Lethargy	672	0
Loss of consciousness	356	2
Postictal state	1	0
Somnolence	340	0
Stupor	1	0
Syncope	1310	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	2	0
Bradykinesia	6	0
Clumsiness	4	0
Dyskinesia	18	0
Extrapyramidal disorder	2	0
Fine motor delay	1	0
Fine motor skill dysfunction	5	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	28	0
Motor dysfunction	4	0
Movement disorder	18	0
Psychomotor hyperactivity	5	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalitis NEC</i>		
Encephalitis allergic	1	0
Encephalitis autoimmune	1	0
Noninfective encephalitis	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	127	0
Facial nerve disorder	2	0
Facial paralysis	70	0
Facial paresis	15	0
Facial spasm	7	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	16	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	2	0
<i>Headaches NEC</i>		
Cluster headache	76	0
Cold-stimulus headache	16	0
Drug withdrawal headache	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Headache	9989	0
Medication overuse headache	1	0
Menstrual headache	2	0
New daily persistent headache	2	0
Occipital neuralgia	2	0
Primary cough headache	2	0
Primary headache associated with sexual activity	2	0
Sinus headache	128	0
Tension headache	198	0
Thunderclap headache	4	0
Vascular headache	8	0
Hydrocephalic conditions		
Hydrocephalus	1	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain oedema	1	0
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	3	0
Lumbar spinal cord and nerve root disorders		
Lumbar radiculopathy	1	0
Sciatica	23	0
Memory loss (excl dementia)		
Amnesia	81	0
Memory impairment	55	0
Transient global amnesia	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	34	0
Disturbance in attention	105	0
Mental impairment	20	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	8	0
Migraine	982	0
Migraine with aura	55	0
Migraine without aura	5	0
Retinal migraine	6	0
Typical aura without headache	1	0
Vestibular migraine	5	0
Mononeuropathies		
Carpal tunnel syndrome	7	0
Cubital tunnel syndrome	1	0
Meralgia paraesthetica	1	0
Mononeuritis	2	0
Nerve compression	4	0
Peroneal nerve palsy	1	0
Sciatic nerve neuropathy	1	0
Motor neurone diseases		
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	6	0
Multiple sclerosis pseudo relapse	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Multiple sclerosis relapse	9	0
Progressive multiple sclerosis	1	0
Uhthoff's phenomenon	1	0
Muscle tone abnormal		
Drop attacks	1	0
Hypotonia	11	0
Stiff leg syndrome	3	0
Myelitis (incl infective)		
Myelitis transverse	8	0
Narcolepsy and hypersomnia		
Hypersomnia	43	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	7	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Hemianopia	1	0
Tunnel vision	13	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	2	0
Dizziness	3970	0
Dizziness exertional	22	0
Dizziness postural	281	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	85	0
Hyporesponsive to stimuli	1	0
Meningism	2	0
Neurological symptom	15	0
Persistent postural-perceptual dizziness	6	0
Presyncope	300	0
Slow response to stimuli	2	0
Tongue biting	2	0
Unresponsive to stimuli	15	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	6	0
Neuromuscular pain	2	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Myasthenic syndrome	1	0
Olfactory nerve disorders		
Anosmia	54	0
Hyposmia	3	0
Parosmia	58	0
Optic nerve disorders NEC		
Optic neuritis	5	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	7	0
Burning sensation	146	0
Dysaesthesia	2	0
Formication	13	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hemianaesthesia	1	0
Hemihypoaesthesia	1	0
Hyperaesthesia	61	0
Hypoaesthesia	772	0
Paraesthesia	1139	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	10	0
Hemiparesis	9	0
Hemiplegia	12	0
Monoparesis	28	0
Monoplegia	38	0
Paralysis	46	0
Paraparesis	2	0
Paresis	2	0
Quadriplegia	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	13	0
Parkinsonism	1	1
Reduced facial expression	1	0
<i>Partial complex seizures</i>		
Focal dyscognitive seizures	2	0
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	2	0
Neuralgic amyotrophy	4	0
Neuritis	3	0
Neuropathy peripheral	23	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	2	0
Small fibre neuropathy	2	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	2	0
Epilepsy	33	0
Febrile convulsion	6	0
Myoclonic epilepsy	1	0
Partial seizures	8	0
Psychogenic seizure	1	0
Seizure	247	0
Seizure anoxic	2	0
Seizure cluster	1	0
Status epilepticus	30	0
Tonic clonic movements	3	0
Tonic convulsion	6	0
<i>Sensory abnormalities NEC</i>		
Ageusia	124	0
Allodynia	4	0
Aura	4	0
Complex regional pain syndrome	1	0
Dysgeusia	256	0
Electric shock sensation	18	0
Hypogeusia	1	0
Loss of proprioception	1	0
Neuralgia	177	0
Post herpetic neuralgia	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Restless legs syndrome	53	0
Sensory disturbance	32	0
Sensory loss	42	0
Taste disorder	61	0
Vibratory sense increased	2	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	10	0
<i>Speech and language abnormalities</i>		
Dysarthria	62	0
Incoherent	12	0
Repetitive speech	1	0
Slow speech	7	0
Speech disorder	26	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radicular pain	1	0
Radiculitis brachial	4	0
Radiculopathy	2	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	43	0
<i>Tremor (excl congenital)</i>		
Essential tremor	2	0
Head titubation	3	0
Tremor	914	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	17	0
Trigeminal neuritis	1	0
<i>Vagus nerve disorders</i>		
Vagus nerve disorder	1	0
Vocal cord paralysis	1	0
<i>Vertigos NEC</i>		
Vertigo CNS origin	1	0
Nervous system disorders SOC TOTAL	24827	11

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	74	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	4	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	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	5	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	5	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	117	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	3	0
Stent malfunction	1	0
Thrombosis in device	4	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	8	0
<i>Product physical issues</i>		
Product after taste	1	0
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
<i>Product supply and availability issues</i>		
Product availability issue	2	0
null SOC TOTAL	38	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	7	0
Breath holding	4	0
Staring	1	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Constricted affect	2	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	31	0
Anxiety	296	0
Nervousness	63	0
Stress	28	0
Tension	11	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	5	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Disinhibition	1	0
Homicidal ideation	1	0
Impatience	1	0
Paranoia	8	0
Personality change	3	0
Social avoidant behaviour	1	0
Soliloquy	1	0
Violence-related symptom	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
Distractibility	1	0
Mental fatigue	71	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	308	0
Disorientation	119	0
<i>Deliria</i>		
Delirium	73	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	111	0
Depression suicidal	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Major depression	4	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	5	0
Dissociation	14	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	8	0
Insomnia	586	0
Middle insomnia	14	0
Terminal insomnia	13	0
<i>Dyssomnias</i>		
Poor quality sleep	113	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
Eating disorder	2	0
<i>Emotional and mood disturbances NEC</i>		
Anger	17	0
Emotional disorder	22	0
Emotional distress	12	0
Emotional poverty	1	0
Euphoric mood	12	0
Frustration tolerance decreased	5	0
Irritability	57	0
Mood altered	22	0
<i>Factitious disorders</i>		
Factitious disorder	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Astraphobia	1	0
Fear	13	0
Fear of death	1	0
Fear of eating	1	0
Fear of injection	6	0
Paruresis	1	0
Phobia	1	0
Phonophobia	2	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	19	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	165	0
Hallucination, auditory	7	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	7	0
Hallucinations, mixed	3	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	66	0
<i>Mental disorders NEC</i>		
Mental disorder	4	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	4	0
Depressed mood	114	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Feeling of despair	6	0
Negative thoughts	2	0
Sense of a foreshortened future	1	0
Tearfulness	7	0
Mood alterations with manic symptoms		
Mania	5	0
Mood disorders NEC		
Affective disorder	3	0
Apathy	15	0
Listless	14	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Obsessive-compulsive disorders and symptoms		
Dermatophagia	3	0
Orgasmic disorders and disturbances		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	62	0
Panic disorder	1	0
Panic reaction	16	0
Paraphilias and paraphilic disorders		
Exhibitionism	1	0
Parasomnias		
Abnormal dreams	49	0
Abnormal sleep-related event	1	0
Exploding head syndrome	1	0
Nightmare	73	0
Sleep inertia	1	0
Sleep talking	4	0
Sleep terror	6	0
Somnambulism	2	0
Perception disturbances NEC		
Autoscopy	3	0
Deja vu	1	0
Derealisation	3	0
Illusion	1	0
Near death experience	1	0
Psychiatric elimination disorders		
Enuresis	15	0
Psychiatric symptoms NEC		
Decreased eye contact	1	0
Helplessness	1	0
Hypervigilance	3	0
Psychiatric symptom	6	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	3	0
Sexual arousal disorders		
Disturbance in sexual arousal	1	0
Sexual desire disorders		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Libido decreased	6	0
Libido increased	1	0
Loss of libido	7	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	91	0
Sleep disorder due to general medical condition, insomnia type	1	0
Somatic symptom disorders		
Conversion disorder	7	0
Habit cough	9	0
Speech and language usage disturbances		
Disorganised speech	3	0
Speech articulation and rhythm disturbances		
Dysphemia	4	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	4	0
Head banging	7	0
Stress disorders		
Acute stress disorder	1	0
Burnout syndrome	1	0
Post-traumatic stress disorder	1	0
Substance related and addictive disorders		
Alcoholism	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	2	0
Suicidal behaviour	2	0
Suicidal ideation	24	0
Suicide attempt	4	0
Suspected suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	5	0
Intrusive thoughts	1	0
Tachyphrenia	6	0
Thinking abnormal	8	0
Thought blocking	2	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	3025	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	2	0
Bladder pain	12	0
Dysuria	15	0
Incontinence	27	0
Micturition urgency	19	0
Mixed incontinence	1	0
Pollakiuria	55	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	33	0
Urinary retention	12	0
Urinary straining	2	0
Urine flow decreased	2	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	6	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
Glomerulonephritis membranous	1	0
IgA nephropathy	2	0
Nephrotic syndrome	1	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	5	0
Loss of bladder sensation	3	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal disorders NEC</i>		
Renal disorder	3	0
<i>Renal failure and impairment</i>		
Acute kidney injury	11	0
Chronic kidney disease	3	0
Oliguria	1	0
Renal failure	2	0
Renal impairment	5	0
Renal injury	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vein occlusion	1	0
Renal vein thrombosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	28	0
Haematuria	15	0
Loin pain haematuria syndrome	1	0
Urine abnormality	5	0
Urine odour abnormal	4	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	10	0
Nocturia	2	0
Polyuria	2	0
Renal pain	133	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	439	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

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	22	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	2	0
Breast oedema	1	0
Breast pain	171	0
Breast swelling	25	0
Breast tenderness	18	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	11	0
Premature menopause	5	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	26	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	490	0
Intermenstrual bleeding	268	0
Menstrual discomfort	4	0
Menstrual disorder	438	0
Menstruation irregular	712	0
Premenstrual dysphoric disorder	1	0
Premenstrual pain	23	0

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Report Run Date: 24-Nov-2022
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Premenstrual syndrome	21	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	110	0
Hypomenorrhoea	121	0
Menstruation delayed	871	0
Oligomenorrhoea	37	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1101	0
Menometrorrhagia	9	0
Polymenorrhoea	183	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	8	0
Polycystic ovaries	11	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovulation pain	21	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	22	0
Pelvic haemorrhage	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile pain	1	0
Penis disorder	4	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	2	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital blister	1	0
Genital haemorrhage	4	0
Genital paraesthesia	1	0
Genital ulceration	3	0
Perineal ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital odour	1	0
Genital pain	4	0
Genital rash	1	0
Pelvic discomfort	1	0
Pelvic pain	41	0
<i>Scrotal disorders NEC</i>		
Scrotal dermatitis	1	0
Scrotal pain	8	0
Scrotal swelling	1	0
Varicocele	3	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	5	0
Infertility female	1	0
Sexual dysfunction	2	0
<i>Spermatogenesis and semen disorders</i>		
Haematospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0

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Report Run Date: 24-Nov-2022
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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Testicular mass	1	0
Testicular pain	22	0
Testicular swelling	7	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	22	0
Metrorrhoea	1	0
Uterine haemorrhage	16	0
Uterine pain	8	0
<i>Uterine neoplasms</i>		
Uterine polyp	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	18	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	372	0
Vaginal ulceration	4	0
Vulval haemorrhage	11	0
Vulval ulceration	5	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	21	0
Vaginal odour	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	5438	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Agonal respiration	1	0
Apnoea	1	0
Dyspnoea	2074	0
Dyspnoea at rest	1	0
Dyspnoea exertional	8	0
Grunting	1	0
Hyperventilation	15	0
Hypopnoea	40	0
Hypoventilation	1	0
Irregular breathing	7	0
Mouth breathing	2	0
Obstructive sleep apnoea syndrome	2	0
Respiration abnormal	26	0
Respiratory arrest	2	1
Respiratory distress	3	0
Sleep apnoea syndrome	5	0
Tachypnoea	8	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	106	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
Cough variant asthma	1	0
Obstructive airways disorder	1	0
Wheezing	169	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	1
Hypoxia	8	0
<i>Coughing and associated symptoms</i>		
Allergic cough	3	0
Cough	829	0
Cough decreased	1	0
Haemoptysis	10	0
Productive cough	52	0
Sputum discoloured	7	0
<i>Diaphragmatic disorders</i>		
Diaphragm muscle weakness	1	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	3	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	2	0
Pneumonitis	8	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Hiccups	18	0
Increased viscosity of bronchial secretion	1	0
Lower respiratory tract congestion	2	0
Pleuritic pain	7	0
Pulmonary haemorrhage	1	0
Pulmonary pain	37	0
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	91	0
Nasal inflammation	1	0
Rhinitis allergic	1	0
Vasomotor rhinitis	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	240	0
Nasal crusting	1	0
Nasal dryness	3	0
Nasal odour	1	0
Nasal oedema	2	0
Nasal pruritus	4	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	6	0
Sinus congestion	16	0
Sinus disorder	5	0
<i>Parenchymal lung disorders NEC</i>		
Emphysema	1	0
Interstitial lung disease	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	6	0
Pharyngeal oedema	4	0
Pharyngeal paraesthesia	6	0
Pharyngeal swelling	74	0
Tonsillar erythema	3	0
Tonsillar exudate	1	0
Tonsillar hypertrophy	20	0
Tonsillar inflammation	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	11	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	6	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	6	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	111	3
Pulmonary thrombosis	3	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	4	0
<i>Respiratory signs and symptoms NEC</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Diaphragmalgia	5	0
Painful respiration	4	0
Respiratory symptom	4	0
Use of accessory respiratory muscles	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	2	0
Ear, nose and throat disorder	1	0
Lung disorder	2	0
Pulmonary mass	1	0
Respiratory disorder	3	0
Respiratory tract congestion	1	0
Respiratory tract irritation	2	0
Respiratory tract oedema	1	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal inflammation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	26	0
Catarrh	12	0
Choking	9	0
Dry throat	35	0
Dysphonia	37	0
Increased viscosity of upper respiratory secretion	9	0
Nasal discomfort	4	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	8	0
Oropharyngeal pain	757	0
Paranasal sinus discomfort	9	0
Rhinalgia	13	0
Rhinorrhoea	229	0
Sinus pain	85	0
Sneezing	80	0
Snoring	1	0
Throat clearing	2	0
Throat irritation	51	0
Throat tightness	59	0
Upper-airway cough syndrome	6	0
Yawning	11	0
Respiratory disorders SOC TOTAL	5592	5

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	38	0
Acne cystic	2	0
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	93	0
Alopecia areata	21	0
Alopecia totalis	2	0
Diffuse alopecia	1	0
<i>Angioedemas</i>		
Angioedema	83	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	328	0
Hidradenitis	2	0
Hyperhidrosis	1176	0
Miliaria	78	0
Night sweats	370	0
<i>Bullous conditions</i>		
Blister	121	0
Blister rupture	2	0
Blood blister	5	0
Dermatitis bullous	6	0
Erythema multiforme	20	0
Pemphigoid	2	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	2	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	121	0
Pain of skin	172	0
Papule	22	0
Scab	7	0
Scar pain	7	0
Sensitive skin	170	0
Skin burning sensation	97	0
Skin discolouration	50	0
Skin discomfort	2	0
Skin disorder	3	0
Skin induration	8	0
Skin lesion	30	0
Skin necrosis	2	0
Skin odour abnormal	6	0
Skin plaque	1	0
Skin reaction	134	0
Skin sensitisation	17	0
Skin swelling	39	0
Skin texture abnormal	2	0
Skin tightness	8	0
Skin warm	259	0
Skin weeping	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Sticky skin	1	0
Yellow skin	5	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	61	0
Dermatitis allergic	133	0
Dermatitis atopic	21	0
Dermatitis contact	11	0
Dyshidrotic eczema	14	0
Eczema	107	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	3	0
Flagellate dermatitis	1	0
Hand dermatitis	1	0
Neurodermatitis	2	0
Seborrhoeic dermatitis	1	0
Skin irritation	47	0
<i>Dermatitis ascribed to specific agent</i>		
Bromoderma	1	0
Drug eruption	5	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Severe cutaneous adverse reaction	1	0
<i>Erythemas</i>		
Erythema	1367	0
Vancomycin infusion reaction	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	2	1
Exfoliative rash	4	0
Skin exfoliation	26	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
<i>Hyperpigmentation disorders</i>		
Ephelides	2	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Skin hypopigmentation	2	0
Vitiligo	4	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
Nail disorder	1	0
Nail ridging	1	0
Onychalgia	1	0
Onychoclasia	3	0
Onychomadesis	1	0
Splinter haemorrhages	1	0
<i>Panniculitides</i>		
Erythema nodosum	12	0
<i>Papulosquamous conditions</i>		
Lichen planus	5	0
Lichen sclerosus	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Parapsoriasis	2	0
Pityriasis rosea	25	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	27	0
Pigmentation changes NEC		
Pigmentation disorder	3	0
Pilar disorders NEC		
Hair colour changes	1	0
Hair growth abnormal	2	0
Hair texture abnormal	1	0
Piloerection	16	0
Trichodynia	1	0
Trichorrhexis	1	0
Pruritus NEC		
Itching scar	4	0
Pruritus	2791	0
Psoriatic conditions		
Guttate psoriasis	4	0
Palmoplantar pustulosis	1	0
Psoriasis	48	0
Rebound psoriasis	1	0
Purpura and related conditions		
Henoch-Schonlein purpura	3	0
Petechiae	29	0
Purpura	20	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	3231	0
Rash erythematous	1277	0
Rash macular	226	0
Rash maculo-papular	9	0
Rash morbilliform	11	0
Rash papular	212	0
Rash pruritic	700	0
Rash vesicular	16	0
Systemic lupus erythematosus rash	1	0
Rosaceas		
Erythematotelangiectatic rosacea	1	0
Rosacea	3	0
Scaly conditions		
Pityriasis	6	0
Sebaceous gland disorders		
Seborrhoea	2	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	5	0
Skin mass	13	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	10	0
Skin ulcer	7	0
Skin cysts and polyps		
Dermal cyst	8	0
Skin dystrophies		
Keloid scar	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin wrinkling	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	2	0
Skin haemorrhage	7	0
Skin hypoplasias and atrophies		
Skin atrophy	3	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	1	0
Needle track marks	2	0
Skin vasculitides		
Capillaritis	2	0
Cutaneous vasculitis	4	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	5	0
Skin vasomotor conditions		
Livedo reticularis	6	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	6	0
Cold urticaria	1	0
Idiopathic urticaria	5	0
Mechanical urticaria	29	0
Urticaria	849	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	8	0
Urticaria contact	1	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	15036	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	2	0
Menopause	11	0
Postmenopause	2	0
<i>Disability issues</i>		
Bedridden	18	0
Disability	1	0
Housebound	1	0
Immobile	11	0
Impaired driving ability	2	0
Impaired work ability	5	0
Loss of personal independence in daily activities	18	0
Sight disability	2	0
Walking aid user	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>		
Impaired quality of life	2	0
Social problem	1	0
Tattoo	1	0
Social circumstances SOC TOTAL	89	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Light anaesthesia	1	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	2	0
<i>Contraceptive methods female</i>		
Post coital contraception	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Eye therapeutic procedures NEC</i>		
Eye irrigation	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	5	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	3	0
<i>Haematological therapeutic procedures NEC</i>		
Bone marrow transplant	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	43	0
Immunisation	24	0
Influenza immunisation	1	0
Vaccine coadministration	1	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	3	0
<i>Male genital tract therapeutic procedures NEC</i>		
Vasoligation	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	4	0
<i>Therapeutic procedures NEC</i>		
Anaphylaxis treatment	2	0
Bed rest	6	0
Botulinum toxin injection	1	0
Hospitalisation	7	0
Injection	19	0
Interchange of vaccine products	86	0
Mass excision	2	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	225	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive urgency	1	0
Malignant hypertension	2	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm ruptured	1	0
Artery dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic thrombosis	2	1
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic stenosis	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	5	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	5	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	17	0
Neurogenic shock	1	0
Shock	8	0
<i>Haemorrhages NEC</i>		
Bloody discharge	2	0
Haematoma	12	0
Haemorrhage	252	0
Internal haemorrhage	3	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	42	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	6	0
Embolism venous	1	0
Thrombosis	91	1
Venous thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Haemorrhagic infarction	1	0
Infarction	1	0
Ischaemia	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Arterial fibrosis	1	0
Vascular pain	9	0
Vasodilatation	4	0
Vein discolouration	1	0
Vein rupture	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	9	0
Deep vein thrombosis	79	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Moderna Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Pelvic venous thrombosis	2	0
Superficial vein thrombosis	5	0
Thrombophlebitis	8	0
Peripheral vascular disorders NEC		
Cyanosis	16	0
Erythromelalgia	1	0
Flushing	71	0
Hot flush	366	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Extremity necrosis	1	0
Peripheral coldness	133	0
Peripheral ischaemia	2	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	17	0
Phlebitis NEC		
Phlebitis	4	0
Phlebitis superficial	1	0
Site specific vascular disorders NEC		
Pallor	99	0
Varicose veins NEC		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	8	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Hypertension	165	0
Prehypertension	1	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	2	0
Hypotension	139	0
Orthostatic hypotension	6	0
Vasculitides NEC		
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	17	0
Vena caval embolism and thrombosis		
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1643	2
TOTAL REACTIONS FOR DRUG	151628	111
TOTAL REPORTS	47045	
TOTAL FATAL OUTCOME REPORTS		111