

# COVID-19 Moderna Vaccine Analysis Print

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All UK spontaneous reports received up to and including F1 EGG for COVID-19 Moderna vaccine analysis print

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## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Iron deficiency anaemia	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	8	0
Microcytic anaemia	1	0
<i><b>Anaemias haemolytic NEC</b></i>		
Haemolytic anaemia	1	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	6	0
Spontaneous haematoma	1	0
<i><b>Coagulopathies</b></i>		
Antiphospholipid syndrome	2	0
Coagulopathy	3	0
Hypercoagulation	1	0
<i><b>Eosinophilic disorders</b></i>		
Eosinophilia	2	0
<i><b>Haematological disorders</b></i>		
Blood disorder	1	0
Mast cell activation syndrome	2	0
Mastocytosis	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	337	0
Lymph node ulcer	1	0
Lymphadenitis	25	0
Lymphadenopathy	1999	0
Lymphatic disorder	1	0
<i><b>Neutropenias</b></i>		
Autoimmune neutropenia	1	0
Neutropenia	3	0
<i><b>Polycythaemia (excl rubra vera)</b></i>		
Stress polycythaemia	1	0
<i><b>Sickle cell trait and disorders</b></i>		
Sickle cell anaemia with crisis	1	0
<i><b>Spleen disorders</b></i>		
Splenic infarction	1	0
Splenic vein thrombosis	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	7	0
Thrombocytopenia	27	0
Thrombocytopenic purpura	2	0
<b>Blood disorders SOC TOTAL</b>	<b>2437</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	3	0
Bundle branch block left	1	0
Bundle branch block right	2	0
Sinoatrial block	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	15	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	2	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	3	0
Palpitations	1576	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	1	0
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
<i><b>Coronary artery disorders NEC</b></i>		
Arteriosclerosis coronary artery	1	1
Coronary artery disease	1	0
Coronary artery occlusion	1	0
Coronary artery stenosis	1	0
Coronary artery thrombosis	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	5	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	1	0
Acute myocardial infarction	2	0
Angina pectoris	60	0
Angina unstable	2	0
Myocardial infarction	27	0
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	1	0
<i><b>Mitral valvular disorders</b></i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	7	0
Left ventricular dysfunction	3	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
Myocardial oedema	1	0
<i><b>Noninfectious myocarditis</b></i>		
Hypersensitivity myocarditis	1	0
Myocarditis	206	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	115	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial effusion	3	0
Pericardial rub	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b> Cardiac disorders cont'd		
Arrhythmia	29	0
Bradycardia	13	0
Cardiac fibrillation	1	0
Cardiac flutter	129	0
Extrasystoles	45	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachyarrhythmia	3	0
Tachycardia	702	1
Tachycardia foetal	1	0
<b><i>Supraventricular arrhythmias</i></b>		
Atrial fibrillation	32	0
Atrial flutter	11	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	10	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	6	0
<b><i>Ventricular arrhythmias and cardiac arrest</i></b>		
Cardiac arrest	13	4
Ventricular extrasystoles	4	0
Ventricular tachycardia	5	0
<b>Cardiac disorders SOC TOTAL</b>	<b>3063</b>	<b>6</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	3	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>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
<b>Congenital disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	7	0
Ear discomfort	8	0
Ear disorder	5	0
Ear inflammation	1	0
Ear pain	285	0
Ear swelling	6	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	50	0
Deafness transitory	1	0
Deafness unilateral	7	0
Hypoacusis	41	0
Sudden hearing loss	12	0
<i>Hyperacusia</i>		
Hyperacusis	9	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	3	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	18	0
Tinnitus	392	0
Vertigo	281	0
Vertigo labyrinthine	2	0
Vertigo positional	12	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>1149</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	1	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	7	0
Ovulation delayed	11	0
<i>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 pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	4	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	4	0
<b>Endocrine disorders SOC TOTAL</b>	<b>48</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	3	0
<i><b>Cataract conditions</b></i>		
Cataract	1	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Chorioretinopathy	3	0
Vitreous detachment	2	0
Vitreous floaters	16	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	1	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	8	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	35	0
Eyelid ptosis	3	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iridocyclitis	2	0
Iritis	2	0
Uveitis	11	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	33	0
Lacrimation increased	15	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	2	0
Erythema of eyelid	2	0
Eyelid cyst	1	0
Eyelid irritation	1	0
Eyelid oedema	2	0
Eyelid rash	2	0
Swelling of eyelid	33	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Lagophthalmos	1	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haematoma	1	0
Eye haemorrhage	4	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	3	0
Eye oedema	1	0
Eye pain	330	0
Eye swelling	128	0
Eyelid disorder	2	0
Eyelids pruritus	2	0
Ocular discomfort	11	0
Periorbital oedema	3	0
Periorbital swelling	19	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	3	0
Eye discharge	2	0
Eye inflammation	7	0
Eye irritation	18	0
Eye pruritus	38	0
Ocular hyperaemia	42	0
<i><b>Ocular nerve and muscle disorders</b></i>		



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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Extraocular muscle paresis	1	0
Eye movement disorder	7	0
Gaze palsy	1	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	2	0
Asthenopia	27	0
Foreign body sensation in eyes	7	0
Hypoaesthesia eye	6	0
Photophobia	130	0
<b>Optic disc abnormalities NEC</b>		
Optic discs blurred	1	0
Papilloedema	1	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic ischaemic neuropathy	1	0
<b>Orbital infections, inflammations and irritations</b>		
Orbital myositis	1	0
<b>Orbital structural change, deposit and degeneration</b>		
Lid sulcus deepened	2	0
<b>Pupil disorders</b>		
Mydriasis	3	0
<b>Refractive and accommodative disorders</b>		
Accommodation disorder	1	0
Astigmatism	3	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	8	0
<b>Retinal structural change, deposit and degeneration</b>		
Retinal detachment	1	0
<b>Retinopathies NEC</b>		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
<b>Scleral infections, irritations and inflammations</b>		
Episcleritis	5	0
<b>Scleral structural change, deposit and degeneration</b>		
Scleral disorder	1	0
<b>Structural change, deposit and degeneration of eye NEC</b>		
Exophthalmos	2	0
<b>Visual colour distortions</b>		
Cyanopsia	1	0
Xanthopsia	2	0
<b>Visual disorders NEC</b>		
Diplopia	29	0
Halo vision	4	0
Metamorphopsia	5	0
Photopsia	31	0
Scintillating scotoma	1	0
Vision blurred	291	0
<b>Visual field disorders</b>		
Visual field defect	5	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Blindness	32	0
Blindness transient	5	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Blindness unilateral	1	0
Night blindness	1	0
Visual acuity reduced	3	0
Visual impairment	51	0
<b>Eye disorders SOC TOTAL</b>	<b>1470</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	3	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	7	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	6	0
Colitis ischaemic	1	0
Colitis ulcerative	7	0
Crohn's disease	8	0
Inflammatory bowel disease	4	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teething	2	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Dental paraesthesia	5	0
Hyperaesthesia teeth	6	0
Toothache	35	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1101	0
Diarrhoea haemorrhagic	5	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	145	0
Epigastric discomfort	3	0
Eructation	19	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	10	0
Faeces soft	1	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	73	0
Flatulence	39	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	10	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal pain	325	0
Abdominal pain lower	24	0
Abdominal pain upper	837	0
Abdominal rigidity	3	0
Abdominal tenderness	5	0
Gastrointestinal pain	34	0
Oesophageal pain	1	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	41	0
Gastric dilatation	2	0
Gastrooesophageal reflux disease	37	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Food poisoning	2	0
Functional gastrointestinal disorder	3	0
Gastric disorder	1	0
Gastrointestinal disorder	3	0
Lymphoid hyperplasia of intestine	1	0
Stomach mass	1	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	1	0
Change of bowel habit	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Gastrointestinal inflammation	1	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Hyperchlorhydria	2	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	158	0
Acute abdomen	1	0
Anal incontinence	3	0
Breath odour	8	0
Dysphagia	33	0
Odynophagia	8	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	1	0
Frequent bowel movements	6	0
Irritable bowel syndrome	17	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	1	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	2	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	2	0
Mesenteric vein thrombosis	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	19	0
Gingival swelling	7	0
Noninfective gingivitis	2	0
<b><i>Gingival haemorrhages</i></b>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Gingival bleeding	14	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoids	6	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	1	0
Rectal haemorrhage	17	0
<b><i>Malabsorption syndromes</i></b>		
Coeliac disease	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Discoloured vomit	1	0
Nausea	4521	0
Regurgitation	1	0
Retching	30	0
Vomiting	1711	0
Vomiting projectile	19	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	3	0
Haematemesis	8	0
Haematochezia	14	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
<b><i>Oesophagitis (excl infective)</i></b>		
Oesophagitis	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Aptyalism	1	0
Dry mouth	102	0
Lip dry	9	0
Saliva altered	2	0
Salivary hypersecretion	12	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Chapped lips	2	0
Cheilitis	4	0
Enlarged uvula	1	0
Lip blister	3	0
Lip disorder	1	0
Oral disorder	1	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	4	0
Oral blood blister	4	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Coating in mouth	2	0
Hypoaesthesia oral	88	0
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	11	0
Lip pruritus	3	0
Oral discomfort	11	0
Oral mucosal blistering	2	0
Oral mucosal eruption	2	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	33	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Oral pruritus	2	0
Paraesthesia oral	124	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	1	0
Lip swelling	204	0
Mouth swelling	23	0
<b>Peptic ulcers and perforation</b>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	3	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Rectal inflammations NEC</b>		
Proctitis	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland mass	1	0
Salivary gland pain	3	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	3	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	4	0
Lip ulceration	4	0
Mouth ulceration	94	0
Stomatitis	6	0
<b>Tongue disorders</b>		
Glossitis	7	0
Tongue disorder	9	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
<b>Tongue signs and symptoms</b>		
Glossodynia	30	0
Stiff tongue	1	0
Swollen tongue	90	0
Tongue blistering	2	0
Tongue coated	5	0
Tongue discolouration	3	0
Tongue discomfort	5	0
Tongue dry	3	0
Tongue eruption	1	0
Tongue movement disturbance	1	0
Tongue oedema	3	0
Tongue pruritus	1	0
Tongue spasm	1	0
<b>Tooth missing</b>		
Tooth loss	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>10410</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	1	0
Administration site erythema	1	0
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Administration site reaction	2	0
Administration site warmth	1	0
Puncture site bruise	6	0
Puncture site pain	4	0
Vessel puncture site bruise	2	0
<b><i>Adverse effect absent</i></b>		
No adverse event	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	11	0
Application site inflammation	1	0
Application site joint erythema	1	0
Application site pain	3	0
Application site pruritus	10	0
Application site rash	1	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	4	0
<b><i>Asthenic conditions</i></b>		
Asthenia	567	0
Chronic fatigue syndrome	9	0
Decreased activity	1	0
Fatigue	6281	0
Malaise	1084	0
Sluggishness	2	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	2	0
Hypothermia	5	0
Temperature regulation disorder	3	0
<b><i>Complications associated with device NEC</i></b>		
Injury associated with device	1	0
<b><i>Death and sudden death</i></b>		
Death	16	16
Sudden death	2	2
<b><i>Febrile disorders</i></b>		
Pyrexia	6635	1
<b><i>Feelings and sensations NEC</i></b>		
Chills	3973	0
Feeling abnormal	437	0
Feeling cold	380	0
Feeling drunk	17	0
Feeling hot	358	0
Feeling jittery	11	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Feeling of body temperature change	122	0
Hangover	21	0
Hunger	18	0
Sensation of blood flow	1	0
Sensation of foreign body	8	0
Temperature intolerance	22	0
Thirst	117	0
Thirst decreased	1	0
<b>Fibrosis NEC</b>		
Fibrosis	1	0
<b>Gait disturbances</b>		
Gait disturbance	33	0
Gait inability	16	0
Loss of control of legs	4	0
<b>General signs and symptoms NEC</b>		
Condition aggravated	37	0
Crepitations	1	0
Crying	37	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	6	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	641	0
Induration	10	0
Influenza like illness	779	0
Irritability postvaccinal	1	0
Local reaction	27	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2162	0
Screaming	8	0
Secretion discharge	2	0
Swelling	1219	0
Swelling face	203	0
<b>Implant and catheter site reactions</b>		
Catheter site related reaction	1	0
Implant site warmth	3	0
<b>Inflamations</b>		
Granuloma	1	0
Inflammation	194	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	2	0
<b>Infusion site reactions</b>		
Infusion site erythema	2	0
Infusion site mass	1	0
Infusion site pain	5	0
Infusion site pruritus	2	0
Infusion site urticaria	5	0



## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Infusion site warmth	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	9	0
Injection site bruising	14	0
Injection site cyst	1	0
Injection site dermatitis	1	0
Injection site discolouration	1	0
Injection site erythema	211	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	15	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	2	0
Injection site mass	209	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site oedema	6	0
Injection site pain	851	0
Injection site paraesthesia	2	0
Injection site plaque	1	0
Injection site pruritus	134	0
Injection site rash	210	0
Injection site reaction	24	0
Injection site swelling	110	0
Injection site urticaria	57	0
Injection site vesicles	3	0
Injection site warmth	103	0
<b>Interactions</b>		
Alcohol interaction	2	0
Drug interaction	2	0
<b>Mass conditions NEC</b>		
Cyst	8	0
Mass	29	0
Nodule	6	0
<b>Mucosal findings abnormal</b>		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema mucosal	1	0
Polyp	1	0
<b>Necrosis NEC</b>		
Necrosis	1	0
<b>Oedema NEC</b>		
Face oedema	8	0
Localised oedema	6	0
Oedema	18	0
Oedema peripheral	13	0
<b>Pain and discomfort NEC</b>		
Axillary pain	898	0
Chest discomfort	438	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Chest pain	1689	0
Discomfort	127	0
Facial discomfort	1	0
Facial pain	41	0
Hernia pain	1	0
Inflammatory pain	6	0
Non-cardiac chest pain	2	0
Pain	2631	0
Tenderness	203	0
Visceral pain	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	76	0
Adverse reaction	6	0
Drug ineffective	15	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
Therapeutic product effect decreased	1	0
Therapeutic response changed	1	0
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	5	0
<b>Ulcers NEC</b>		
Ulcer	5	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	13	0
Vaccination site bruising	27	0
Vaccination site discolouration	2	0
Vaccination site discomfort	9	0
Vaccination site eczema	1	0
Vaccination site erythema	299	0
Vaccination site haemorrhage	5	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	21	0
Vaccination site inflammation	16	0
Vaccination site irritation	3	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site macule	1	0
Vaccination site mass	83	0
Vaccination site movement impairment	19	0
Vaccination site oedema	1	0
Vaccination site pain	382	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	71	0
Vaccination site rash	148	0
Vaccination site reaction	8	0
Vaccination site scar	1	0

# Case Series Drug Analysis Print

## Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site swelling	203	0
Vaccination site urticaria	13	0
Vaccination site vesicles	3	0
Vaccination site warmth	139	0
<b>Withdrawal and rebound effects</b>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	7	0
<b>General disorders SOC TOTAL</b>	<b>35320</b>	<b>20</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	5	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	1	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	1	0
Jaundice	5	0
Jaundice cholestatic	2	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Hepatic cyst	1	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	0
<i><b>Hepatic vascular disorders</b></i>		
Portal vein thrombosis	2	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	12	0
Liver tenderness	2	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	1	0
Hepatic steatosis	1	0
Hepatitis	2	0
Immune-mediated hepatitis	2	0
Liver injury	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>41</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	2	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	351	0
Infusion related hypersensitivity reaction	13	0
Multiple allergies	4	0
Serum sickness	3	0
Serum sickness-like reaction	1	0
Type I hypersensitivity	1	0
Type IV hypersensitivity reaction	13	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	2	0
Allergy to vaccine	12	0
Drug hypersensitivity	13	0
Food allergy	3	0
Milk allergy	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	70	0
Anaphylactic shock	7	0
Anaphylactoid reaction	10	0
<i>Atopic disorders</i>		
Seasonal allergy	16	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	51	0
Immune system disorder	4	0
Immune-mediated adverse reaction	1	0
Sensitisation	4	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>596</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	10	0
Diverticulitis	5	0
Dysentery	1	0
Gastroenteritis	6	0
Peritonitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Bacterial infection	3	0
Cellulitis	77	0
Folliculitis	1	0
Injection site cellulitis	2	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	4	0
<b><i>Bone and joint infections</i></b>		
Arthritis infective	1	0
<b><i>Borrelial infections</i></b>		
Relapsing fever	1	0
<b><i>Breast infections</i></b>		
Breast abscess	2	0
Mastitis	10	0
<b><i>Candida infections</i></b>		
Candida infection	7	0
Oral candidiasis	5	0
Vulvovaginal candidiasis	8	0
<b><i>Cardiac infections</i></b>		
Endocarditis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Central nervous system infection	1	0
Meningitis	3	0
Meningitis aseptic	1	0
<b><i>Coronavirus infections</i></b>		
Asymptomatic COVID-19	1	0
COVID-19	299	0
COVID-19 pneumonia	6	0
Post-acute COVID-19 syndrome	1	0
Suspected COVID-19	3	0
<b><i>Coxiella infections</i></b>		
Q fever	7	0
<b><i>Cytomegaloviral infections</i></b>		
Cytomegalovirus infection	1	0
Cytomegalovirus infection reactivation	2	0
Pneumonia cytomegaloviral	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Gingivitis	2	0
Sialoadenitis	1	0
Tooth abscess	1	0
Tooth infection	2	0
<b><i>Ear infections</i></b>		
Ear infection	10	0
Labyrinthitis	12	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Otitis externa	1	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	1	0
Lice infestation	1	0
<b><i>Enteroviral infections NEC</i></b>		
Hand-foot-and-mouth disease	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	2	0
<b><i>Eye and eyelid infections</i></b>		
Chorioretinitis	1	0
Conjunctivitis	13	0
Eye infection	3	0
Eyelid boil	1	0
Hordeolum	3	0
<b><i>Female reproductive tract infections</i></b>		
Vaginal infection	1	0
<b><i>Flaviviral infections</i></b>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	3	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
<b><i>Fusobacterium infections</i></b>		
Necrotising ulcerative gingivostomatitis	1	0
<b><i>Herpes viral infections</i></b>		
Eczema herpeticum	2	0
Genital herpes	14	0
Herpes ophthalmic	1	0
Herpes simplex	7	0
Herpes simplex reactivation	1	0
Herpes zoster	114	0
Herpes zoster oticus	3	0
Nasal herpes	1	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	91	0
Varicella	3	0
Varicella zoster virus infection	1	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Abscess limb	2	0
Abscess rupture	1	0
Empyema	1	1
Infection	86	0
Injection site infection	1	0
Localised infection	19	0
Lymph gland infection	2	0
Lymph node abscess	3	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Vaccination site infection	5	0
Vaccine breakthrough infection	1	0
Vestibulitis	1	0
Wound infection	1	0
<b><i>Infectious disorders carrier</i></b>		
SARS-CoV-2 carrier	2	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	580	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Atypical pneumonia	1	0
Bronchitis	6	0
Lower respiratory tract infection	64	1
Pleural infection	1	0
Pneumonia	14	1
<b><i>Male reproductive tract infections</i></b>		
Epididymitis	1	0
Orchitis	3	0
<b><i>Mumps viral infections</i></b>		
Mumps	1	0
<b><i>Nematode infections</i></b>		
Enterobiasis	1	0
<b><i>Orthopox viral infections</i></b>		
Vaccinia virus infection	1	0
<b><i>Parvoviral infections</i></b>		
Erythema infectiosum	1	0
<b><i>Rabies viral infections</i></b>		
Rabies	1	1
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	1	0
<b><i>Rubella viral infections</i></b>		
Rubella	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Intestinal sepsis	1	0
Sepsis	5	0
Septic shock	1	0
Urosepsis	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Acne pustular	1	0
Blister infected	1	0
Eczema infected	1	0
Impetigo	6	0
Infected skin ulcer	1	0
Pustule	11	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	14	0
Vaccination site pustule	1	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	10	0
<b><i>Streptococcal infections</i></b>		
Pharyngitis streptococcal	1	0



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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
<i><b>Tinea infections</b></i>		
Body tinea	3	0
Tinea infection	1	0
<i><b>Tuberculous infections</b></i>		
Lymph node tuberculosis	1	0
<i><b>Upper respiratory tract infections</b></i>		
Acute sinusitis	2	0
Chronic sinusitis	1	0
Laryngitis	6	0
Nasopharyngitis	298	0
Peritonsillar abscess	1	0
Pharyngitis	6	0
Rhinitis	8	0
Sinusitis	31	0
Tonsillitis	15	0
Upper respiratory tract infection	2	0
<i><b>Urinary tract infections</b></i>		
Cystitis	11	0
Kidney infection	4	0
Urinary tract infection	38	0
<i><b>Vascular infections</b></i>		
Lymphangitis	2	0
<i><b>Viral infections NEC</b></i>		
Arthritis viral	1	0
Conjunctivitis viral	1	0
Gastroenteritis viral	3	0
Meningitis viral	2	0
Post viral fatigue syndrome	8	0
Sweating fever	57	0
Vestibular neuronitis	4	0
Viral infection	7	0
Viral labyrinthitis	2	0
Viral pharyngitis	6	0
Viral rash	7	0
<b>Infections SOC TOTAL</b>	<b>2180</b>	<b>4</b>

## Case Series Drug Analysis Print

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Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Oral contusion	1	0
Palate injury	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	2	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Anaesthetic complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotrauma	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Joint injury	1	0
<b><i>Cardiovascular injuries</i></b>		
Vascular injury	1	0
<b><i>Cerebral injuries NEC</i></b>		
Concussion	8	0
Subdural haematoma	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	3	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	15	0
<b><i>Cranial nerve injuries</i></b>		
Optic nerve injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	24	0
Foetal exposure during pregnancy	11	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	550	0
Maternal exposure during pregnancy	259	0
Maternal exposure timing unspecified	1	0
<b><i>Exposures to agents or circumstances NEC</i></b>		
Exposure to SARS-CoV-2	3	0
<b><i>Eye injuries NEC</i></b>		
Blindness traumatic	1	0
Eye contusion	2	0
Eye injury	5	0
<b><i>Fractures and dislocations NEC</i></b>		
Compression fracture	1	0
Joint dislocation	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Procedural vomiting	1	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	8	0
Heat stroke	8	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	8	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	15	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	3	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Ligament sprain	2	0
Muscle injury	5	0
Muscle strain	5	0
Tendon injury	2	0
Tendon rupture	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	21	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Procedural dizziness	5	0
<b><i>Non-occupational environmental exposures</i></b>		
Exposure to extreme temperature	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Arthropod bite	4	0
Bite	1	0
Electric shock	6	0
Fall	33	0
Inflammation of wound	2	0
Injury	4	0
Multiple injuries	1	0
Nervous system injury	1	0
Stab wound	1	0
Struck by lightning	1	0
Wound complication	7	0
Wound haemorrhage	2	0
<b><i>Non-site specific procedural complications</i></b>		
Incision site pain	1	0
Infusion related reaction	1	0
Injection related reaction	24	0
Post procedural complication	1	0
Post procedural erythema	1	0
Procedural pain	1	0
<b><i>Occupational exposures</i></b>		
Occupational exposure to toxic agent	1	0
<b><i>Off label uses</i></b>		
Off label use	21	0
<b><i>Overdoses NEC</i></b>		
Overdose	6	0
<b><i>Peripheral nerve injuries</i></b>		
Sciatic nerve injury	1	0
Ulnar nerve injury	1	0
<b><i>Poisoning and toxicity</i></b>		
Systemic toxicity	1	0
Toxicity to various agents	1	0
<b><i>Product administration errors and issues</i></b>		
Accidental overdose	65	0
Expired product administered	46	0
Extra dose administered	3	0
Inappropriate schedule of product administration	57	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	9	0
Incorrect product administration duration	1	0
Incorrect route of product administration	2	0
Poor quality product administered	1	0

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Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Product administered at inappropriate site	4	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	2	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	1	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	1	0
<b>Radiation injuries</b>		
Sunburn	15	0
<b>Renal and urinary tract injuries NEC</b>		
Bladder injury	1	0
<b>Site specific injuries NEC</b>		
Back injury	2	0
Head injury	10	0
Limb injury	43	0
<b>Skin injuries NEC</b>		
Contusion	329	0
Scar	11	0
Scratch	2	0
Skin abrasion	1	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<b>Skull fractures, facial bone fractures and dislocations</b>		
Jaw fracture	1	0
<b>Spinal cord injuries NEC</b>		
Spinal cord injury cervical	1	0
<b>Stoma complications</b>		
Stoma site discomfort	1	0
Stoma site oedema	1	0
<b>Thermal burns</b>		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	13	0
Thermal burns of eye	6	0
<b>Thoracic cage fractures and dislocations</b>		
Sternal fracture	1	0
<b>Vaccination related complications</b>		
Vaccination complication	15	0
<b>Injuries SOC TOTAL</b>	<b>1767</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal medulla tests</i></b>		
Norepinephrine increased	2	0
<b><i>Auditory and vestibular diagnostic procedures</i></b>		
Audiogram abnormal	1	0
<b><i>Bacteria identification and serology (excl mycobacteria)</i></b>		
Campylobacter test positive	1	0
<b><i>Blood counts NEC</i></b>		
Full blood count abnormal	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Blood lactic acid	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	2	0
Oxygen saturation decreased	14	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose	1	0
Blood glucose decreased	2	0
Blood glucose increased	7	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	3	0
Heart sounds	4	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Ejection fraction decreased	1	0
<b><i>Central nervous system imaging procedures</i></b>		
Computerised tomogram head	1	0
<b><i>Chemistry analyses NEC</i></b>		
Histamine abnormal	1	0
<b><i>Cholesterol analyses</i></b>		
Blood cholesterol increased	1	0
Low density lipoprotein increased	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Bleeding time	1	0
Bleeding time abnormal	1	0
Blood fibrinogen	1	0
Coagulation time shortened	1	0
Fibrin D dimer increased	5	0
International normalised ratio decreased	1	0
International normalised ratio increased	1	0
<b><i>Digestive enzymes</i></b>		
Amylase increased	1	0
<b><i>ECG investigations</i></b>		
Electrocardiogram	1	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	3	0
Electrocardiogram change	1	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	13	0
<b><i>Fertility analyses</i></b>		
Semen analysis abnormal	1	0
<b><i>Foetal and neonatal diagnostic procedures</i></b>		

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<b><i>Fungus identification and serology</i></b>		
Fungal test	1	0
<b><i>Gastrointestinal and abdominal imaging procedures</i></b>		
X-ray with contrast upper gastrointestinal tract	1	0
<b><i>Gastrointestinal function diagnostic procedures</i></b>		
Gastric pH decreased	1	0
<b><i>Haematological analyses NEC</i></b>		
Blood viscosity increased	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	256	0
Heart rate abnormal	22	0
Heart rate decreased	14	0
Heart rate increased	385	0
Heart rate irregular	74	0
Heart rate variability decreased	1	0
Maximum heart rate	1	0
Maximum heart rate increased	1	0
Pulse abnormal	1	0
Pulse absent	1	0
Sinus rhythm	3	0
<b><i>Imaging procedures NEC</i></b>		
X-ray	1	0
<b><i>Immunology analyses NEC</i></b>		
Immunology test	1	0
<b><i>Investigations NEC</i></b>		
Blood test abnormal	4	0
Blood test normal	1	0
Polymerase chain reaction positive	2	0
<b><i>Liver function analyses</i></b>		
Alanine aminotransferase increased	6	0
Aspartate aminotransferase	2	0
Bile output	3	0
Blood bilirubin increased	1	0
Liver function test abnormal	7	0
Liver function test increased	1	0
Transaminases increased	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood calcium increased	2	0
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Urine copper	1	0
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
Bone scan	1	0
<b><i>Musculoskeletal and soft tissue tests NEC</i></b>		
Tender joint count	1	0
<b><i>Neurologic diagnostic procedures</i></b>		
Coma scale abnormal	2	0
Electromyogram abnormal	1	0
Sensory level	1	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Visual tracking test	1	0
Visual tracking test abnormal	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	98	0
Body temperature abnormal	11	0
Body temperature decreased	15	0
Body temperature fluctuation	23	0
Body temperature increased	112	0
Breath sounds	1	0
Breath sounds abnormal	1	0
Grip strength	1	0
Grip strength decreased	2	0
Head lag	4	0
Lymph node palpable	5	0
Muscle strength abnormal	2	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	4	0
Respiratory rate decreased	6	0
Respiratory rate increased	10	0
Skin temperature	23	0
Temperature difference of extremities	4	0
Weight decreased	20	0
Weight increased	10	0
<b><i>Pituitary analyses anterior</i></b>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
<b><i>Platelet analyses</i></b>		
Platelet count decreased	10	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	8	0
<b><i>Red blood cell analyses</i></b>		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
<b><i>Renal function analyses</i></b>		
Blood creatinine increased	1	0
<b><i>Reproductive hormone analyses</i></b>		
Blood testosterone decreased	1	0
False negative pregnancy test	1	0
Pregnancy test	1	0
Pregnancy test false positive	1	0
<b><i>Reproductive organ and breast histopathology procedures</i></b>		
Smear cervix	1	0
<b><i>Reproductive organ and breast imaging procedures</i></b>		
Hysteroscopy	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	2	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	1	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Troponin T increased	1	0
Troponin increased	5	0
<b>Therapeutic drug monitoring analyses</b>		
Analgesic drug level	5	0
<b>Thyroid analyses</b>		
Tri-iodothyronine decreased	1	0
<b>Tissue enzyme analyses NEC</b>		
Blood alkaline phosphatase increased	1	0
Blood lactate dehydrogenase increased	1	0
<b>Urinalysis NEC</b>		
Blood urine	5	0
Blood urine present	25	0
Protein urine	1	0
pH urine	1	0
<b>Urinary tract function analyses NEC</b>		
Urine output	11	0
Urine output decreased	1	0
<b>Urinary tract imaging procedures</b>		
Bladder scan	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	2	0
Blood pressure decreased	11	0
Blood pressure diastolic increased	1	0
Blood pressure increased	31	0
Blood pressure measurement	7	0
Blood pressure normal	1	0
<b>Virus identification and serology</b>		
Coronavirus test	4	0
Influenza A virus test	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	7	0
<b>Vitamin analyses</b>		
Blood folate decreased	1	0
<b>White blood cell analyses</b>		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>1428</b>	<b>0</b>



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Report Run Date: 17-Feb-2022

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	2	0
Decreased appetite	411	0
Food craving	2	0
Food refusal	4	0
Hyperphagia	5	0
Hypophagia	2	0
Increased appetite	8	0
Salt craving	1	0
<i><b>Copper metabolism disorders</b></i>		
Copper deficiency	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	5	0
Diabetes mellitus inadequate control	4	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	2	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	19	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	2	0
Food intolerance	2	0
Gluten sensitivity	1	0
Histamine intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	3	0
Abnormal weight gain	7	0
Feeding disorder	46	0
Food aversion	5	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	7	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	9	0
<i><b>Potassium imbalance</b></i>		
Hypokalaemia	2	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	101	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	10	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Folate deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>674</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 17-Feb-2022

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	50	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	9	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	1	0
<i><b>Bone disorders NEC</b></i>		
Bone erosion	1	0
Exostosis	2	0
Jaw cyst	1	0
Jaw disorder	1	0
Medial tibial stress syndrome	1	0
Osteitis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	100	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	96	0
Spinal pain	16	0
<i><b>Bursal disorders</b></i>		
Bursitis	22	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	20	0
<i><b>Connective tissue disorders NEC</b></i>		
Morphoea	1	0
Polymyalgia rheumatica	4	0
Reynold's syndrome	2	0
<i><b>Extremity deformities</b></i>		
Finger deformity	1	0
Foot deformity	2	0
Hand deformity	2	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	2	0
<i><b>Joint related disorders NEC</b></i>		
Hypermobility syndrome	1	0
Joint lock	10	0
Periarthritis	48	0
Rotator cuff syndrome	5	0
Temporomandibular joint syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	2437	0
Joint effusion	1	0
Joint noise	3	0
Joint range of motion decreased	1	0
Joint stiffness	66	0
Joint swelling	77	0
Joint vibration	2	0
Joint warmth	5	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	2	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Muscle infections and inflammations</i></b>		
Myositis	9	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	23	0
Myalgia	3197	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle atrophy	2	0
Muscle discomfort	2	0
Muscle fatigue	103	0
Muscle haemorrhage	1	0
Muscle spasms	474	0
Muscle swelling	16	0
Muscle tightness	28	0
Muscle twitching	88	0
Myosclerosis	1	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	4	0
Nuchal rigidity	5	0
Trismus	9	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	218	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Growth retardation	1	0
Limb mass	2	0
Mastication disorder	2	0
Mobility decreased	17	0
Muscle contracture	1	0
Musculoskeletal disorder	2	0
Musculoskeletal stiffness	455	0
Weight bearing difficulty	1	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Facial asymmetry	2	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Dupuytren's contracture	1	0
Fasciitis	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	783	0
Flank pain	18	0
Limb discomfort	380	0
Musculoskeletal chest pain	61	0
Musculoskeletal discomfort	20	0
Musculoskeletal pain	22	0
Neck pain	465	0
Pain in extremity	3803	1
Sacral pain	1	0
<b><i>Myopathies</i></b>		
Rhabdomyolysis	1	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	5	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	2	0
<b><i>Rheumatoid arthropathies</i></b>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Rheumatoid arthritis	15	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	58	0
Fluctuance	1	0
Groin pain	26	0
Neck mass	13	0
Soft tissue swelling	2	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	4	0
Arthritis reactive	12	0
Axial spondyloarthritis	1	0
<b>Synovial disorders</b>		
Synovial cyst	5	0
<b>Tendon disorders</b>		
Tendon pain	3	0
Tendonitis	6	0
Trigger finger	3	0
<b>Trunk deformities</b>		
Shoulder deformity	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>13379</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>B-cell lymphomas NEC</b></i>		
B-cell lymphoma stage II	1	0
B-cell lymphoma stage III	1	0
<i><b>Breast and nipple neoplasms benign</b></i>		
Benign breast neoplasm	1	0
<i><b>Breast and nipple neoplasms malignant</b></i>		
Breast cancer	3	0
<i><b>Cardiovascular neoplasms benign</b></i>		
Haemangioma	1	0
<i><b>Leukaemias NEC</b></i>		
Leukaemia	1	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	9	0
<i><b>Mediastinal neoplasms malignancy unspecified NEC</b></i>		
Good syndrome	1	0
<i><b>Metastases to specified sites</b></i>		
Metastases to lymph nodes	1	0
<i><b>Metastases to unknown and unspecified sites</b></i>		
Metastasis	1	0
<i><b>Neoplasms malignant site unspecified NEC</b></i>		
Neoplasm malignant	1	0
<i><b>Oesophageal neoplasms malignant</b></i>		
Oesophageal carcinoma	1	0
<i><b>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</b></i>		
Tonsil cancer	2	0
<i><b>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</b></i>		
Bronchial carcinoma	1	0
<i><b>Skin neoplasms benign</b></i>		
Acrochordon	1	0
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	4	0
<i><b>Small intestinal neoplasms malignant</b></i>		
Small intestine adenocarcinoma	1	0
<i><b>Soft tissue neoplasms benign NEC</b></i>		
Lipoma	1	0
<i><b>Urinary tract neoplasms unspecified malignancy NEC</b></i>		
Renal neoplasm	1	0
<i><b>Uterine neoplasms benign</b></i>		
Uterine leiomyoma	2	0
<b>Neoplasms SOC TOTAL</b>	<b>40</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	5	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	15	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
Orthostatic intolerance	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	3	1
Cerebral infarction	1	0
Cerebrovascular accident	32	1
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	0
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	3	0
Ruptured cerebral aneurysm	1	1
Subarachnoid haemorrhage	5	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	3	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervical radiculopathy	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	3	0
Balance disorder	84	0
Coordination abnormal	5	0
Dysstasia	14	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	6	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	13	0
Lethargy	490	0
Loss of consciousness	261	0
Somnolence	261	0
Stupor	1	0
Syncope	1078	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	1	0

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### Name: COVID-19 Moderna Vaccine Analysis Print

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Bradykinesia	4	0
Clumsiness	4	0
Dyskinesia	12	0
Extrapyramidal disorder	2	0
Fine motor delay	1	0
Fine motor skill dysfunction	4	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	19	0
Motor dysfunction	3	0
Movement disorder	12	0
Psychomotor hyperactivity	4	0
<b>Dystonias</b>		
Dystonia	1	0
<b>Encephalitis NEC</b>		
Noninfective encephalitis	1	0
<b>Eye movement disorders</b>		
IVth nerve paresis	1	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	99	0
Facial nerve disorder	1	0
Facial paralysis	54	0
Facial paresis	12	0
Facial spasm	7	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	7	0
<b>Glossopharyngeal nerve disorders</b>		
Glossopharyngeal neuralgia	1	0
<b>Headaches NEC</b>		
Cluster headache	63	0
Cold-stimulus headache	11	0
Drug withdrawal headache	2	0
Headache	7927	0
New daily persistent headache	2	0
Occipital neuralgia	1	0
Primary cough headache	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	100	0
Tension headache	165	0
Thunderclap headache	3	0
Vascular headache	7	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	1	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	3	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	12	0
<b>Memory loss (excl dementia)</b>		
Amnesia	49	0
Memory impairment	34	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Transient global amnesia	1	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	18	0
Disturbance in attention	81	0
Mental impairment	14	0
<b>Migraine headaches</b>		
Basilar migraine	1	0
Hemiplegic migraine	6	0
Migraine	808	0
Migraine with aura	46	0
Migraine without aura	3	0
Retinal migraine	4	0
Typical aura without headache	1	0
Vestibular migraine	4	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	5	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	4	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0
Multiple sclerosis	3	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	5	0
<b>Muscle tone abnormal</b>		
Drop attacks	1	0
Hypotonia	10	0
Stiff leg syndrome	3	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	2	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	27	0
Narcolepsy	1	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	5	0
Psychomotor skills impaired	1	0
<b>Neurologic visual problems NEC</b>		
Tunnel vision	13	0
<b>Neurological signs and symptoms NEC</b>		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	3163	0
Dizziness exertional	11	0
Dizziness postural	208	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	64	0
Meningism	1	0
Neurological symptom	10	0
Persistent postural-perceptual dizziness	2	0
Presyncope	249	0
Tongue biting	2	0
Unresponsive to stimuli	12	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<b><i>Neuromuscular disorders NEC</i></b>		
Muscle contractions involuntary	2	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
<b><i>Neuromuscular junction dysfunction</i></b>		
Myasthenia gravis	1	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	38	0
Hyposmia	2	0
Parosmia	43	0
<b><i>Optic nerve disorders NEC</i></b>		
Optic neuritis	5	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning feet syndrome	5	0
Burning sensation	117	0
Dysaesthesia	1	0
Formication	7	0
Hemianaesthesia	2	0
Hyperaesthesia	54	0
Hypoaesthesia	643	0
Paraesthesia	928	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	2	0
Hemiparesis	4	0
Hemiplegia	8	0
Monoparesis	24	0
Monoplegia	27	0
Paralysis	30	0
Paraparesis	1	0
Paresis	2	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	11	0
Reduced facial expression	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Autoimmune neuropathy	2	0
Neuralgic amyotrophy	3	0
Neuritis	2	0
Neuropathy peripheral	13	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	23	0
Febrile convulsion	5	0
Myoclonic epilepsy	1	0
Partial seizures	7	0
Psychogenic seizure	1	0
Seizure	179	0
Seizure anoxic	1	0
Seizure cluster	1	0
Status epilepticus	28	0
Tonic clonic movements	3	0
Tonic convulsion	5	0
<b><i>Sensory abnormalities NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Ageusia	86	0
Allodynia	3	0
Aura	3	0
Complex regional pain syndrome	1	0
Dysgeusia	219	0
Electric shock sensation	13	0
Hypogeusia	1	0
Neuralgia	133	0
Post herpetic neuralgia	2	0
Restless legs syndrome	43	0
Sensory disturbance	20	0
Sensory loss	32	0
Taste disorder	48	0
Vibratory sense increased	1	0
<b><i>Sleep disturbances NEC</i></b>		
Sleep deficit	5	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	31	0
Incoherent	10	0
Slow speech	5	0
Speech disorder	15	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculitis brachial	3	0
Radiculopathy	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	19	0
<b><i>Tremor (excl congenital)</i></b>		
Essential tremor	1	0
Head titubation	2	0
Tremor	638	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	6	0
<b>Nervous system disorders SOC TOTAL</b>	<b>19322</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	62	0
<i><b>Foetal complications NEC</b></i>		
Foetal hypokinesia	3	0
Hydrops foetalis	1	0
<i><b>Foetal growth complications</b></i>		
Foetal growth restriction	1	0
<i><b>Gestational age and weight conditions</b></i>		
Premature baby	1	0
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Premature separation of placenta	1	0
<i><b>Labour onset and length abnormalities</b></i>		
Premature labour	4	0
<i><b>Maternal complications of labour NEC</b></i>		
Uterine atony	1	0
Uterine hypertonus	2	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
Somatic symptom disorder of pregnancy	1	0
<i><b>Multiple pregnancies</b></i>		
Twin pregnancy	1	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Live birth	2	0
Pregnancy	4	0
<i><b>Postpartum complications NEC</b></i>		
Postpartum haemorrhage	1	0
<i><b>Pregnancy complicated by maternal disorders</b></i>		
Gestational diabetes	1	0
<i><b>Stillbirth and foetal death</b></i>		
Stillbirth	1	1
<i><b>Umbilical cord complications</b></i>		
Umbilical cord thrombosis	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>93</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device expulsion	1	0
Device leakage	1	0
<b><i>Device malfunction events NEC</i></b>		
Oversensing	1	0
Thrombosis in device	2	0
Undersensing	2	0
<b><i>Manufacturing materials issues</i></b>		
Manufacturing materials issue	1	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination physical	8	0
Suspected product contamination	1	0
<b><i>Product label issues</i></b>		
Product label issue	1	0
<b><i>Product physical issues</i></b>		
Product after taste	1	0
Product taste abnormal	1	0
<b><i>Product quality issues NEC</i></b>		
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	2	0
<b>null SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	6	0
Breath holding	2	0
Staring	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	2	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	3	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	2	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	1	0
Separation anxiety disorder	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	21	0
Anxiety	246	0
Nervousness	46	0
Stress	21	0
Tension	10	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	4	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	1	0
Disinhibition	1	0
Homicidal ideation	1	0
Impatience	1	0
Paranoia	6	0
Personality change	2	0
Social avoidant behaviour	1	0
Violence-related symptom	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Distractibility	1	0
Mental fatigue	58	0
<b><i>Communications disorders</i></b>		
Mutism	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	206	0
Disorientation	83	0
<b><i>Deliria</i></b>		
Delirium	49	0
<b><i>Delusional disorders</i></b>		
Alice in wonderland syndrome	1	0
<b><i>Delusional symptoms</i></b>		
Delusion	2	0
Delusion of parasitosis	1	0
<b><i>Depressive disorders</i></b>		
Depression	90	0
Depression suicidal	4	0
Major depression	3	0
Mixed anxiety and depressive disorder	1	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	2	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Dissociation	13	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	7	0
Insomnia	473	0
Middle insomnia	14	0
Terminal insomnia	13	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	92	0
<b><i>Eating disorders NEC</i></b>		
Binge eating	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	14	0
Emotional disorder	21	0
Emotional distress	11	0
Emotional poverty	1	0
Euphoric mood	12	0
Frustration tolerance decreased	3	0
Irritability	52	0
Mood altered	18	0
<b><i>Factitious disorders</i></b>		
Factitious disorder	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	5	0
Fear of death	1	0
Fear of eating	1	0
Fear of injection	6	0
Paruresis	1	0
Phobia	1	0
Phonophobia	1	0
Social fear	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	17	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	117	0
Hallucination, auditory	6	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	4	0
Hallucinations, mixed	1	0
Somatic hallucination	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	59	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	4	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Decreased interest	1	0
Depressed mood	91	0
Feeling of despair	5	0
Negative thoughts	1	0
Sense of a foreshortened future	1	0
Tearfulness	7	0
<b><i>Mood alterations with manic symptoms</i></b>		
Mania	4	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<b><i>Mood disorders NEC</i></b>		
Affective disorder	1	0
Apathy	12	0
Listless	7	0
<b><i>Narcolepsy and associated conditions</i></b>		
Hypnagogic hallucination	1	0
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Dermatophagia	1	0
<b><i>Orgasmic disorders and disturbances</i></b>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<b><i>Panic attacks and disorders</i></b>		
Limited symptom panic attack	1	0
Panic attack	55	0
Panic reaction	12	0
<b><i>Paraphilias and paraphilic disorders</i></b>		
Exhibitionism	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	38	0
Abnormal sleep-related event	1	0
Nightmare	58	0
Sleep inertia	1	0
Sleep talking	2	0
Sleep terror	5	0
Somnambulism	1	0
<b><i>Perception disturbances NEC</i></b>		
Autoscopy	3	0
Deja vu	1	0
Derealisation	3	0
Illusion	1	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	13	0
<b><i>Psychiatric symptoms NEC</i></b>		
Helplessness	1	0
Hypervigilance	2	0
Psychiatric symptom	4	0
Psychological trauma	1	0
<b><i>Psychotic disorder NEC</i></b>		
Acute psychosis	1	0
Psychotic disorder	2	0
<b><i>Sexual desire disorders</i></b>		
Libido decreased	6	0
Libido increased	1	0
Loss of libido	5	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	74	0
<b><i>Somatic symptom disorders</i></b>		
Conversion disorder	4	0
Habit cough	7	0
<b><i>Speech and language usage disturbances</i></b>		
Disorganised speech	1	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	3	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Lack of spontaneous speech	1	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	4	0
Head banging	6	0
<b><i>Stress disorders</i></b>		
Acute stress disorder	1	0
Post-traumatic stress disorder	1	0
<b><i>Substance related and addictive disorders</i></b>		
Alcoholism	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	19	0
Suicide attempt	2	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	4	0
Intrusive thoughts	1	0
Tachyphrenia	3	0
Thinking abnormal	4	0
Thought blocking	1	0
<b><i>Tic disorders</i></b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>2355</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder irritation	1	0
Bladder pain	10	0
Dysuria	9	0
Incontinence	10	0
Micturition urgency	11	0
Pollakiuria	41	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	13	0
Urinary retention	6	0
Urinary straining	1	0
Urine flow decreased	1	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	2	0
Urinary bladder haemorrhage	2	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	1	0
<i><b>Genitourinary tract infections and inflammations NEC</b></i>		
Urinary tract inflammation	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis acute	1	0
IgA nephropathy	2	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	1	0
Hypertonic bladder	2	0
Loss of bladder sensation	1	0
<i><b>Nephritis NEC</b></i>		
Nephritis	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	6	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	2	0
Renal impairment	2	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	20	0
Haematuria	9	0
Loin pain haematuria syndrome	1	0
Urine abnormality	5	0
Urine odour abnormal	3	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	8	0
Nocturia	1	0
Renal pain	103	0
Urinary tract pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>283</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	6	0
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	4	0
Breast mass	18	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	4	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	3	0
Breast discomfort	2	0
Breast haemorrhage	1	0
Breast oedema	1	0
Breast pain	144	0
Breast swelling	22	0
Breast tenderness	13	0
Nipple pain	2	0
Nipple swelling	2	0
<i><b>Cervix disorders NEC</b></i>		
Cervix haemorrhage uterine	1	0
Ectropion of cervix	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	14	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><b>Gender disorders</b></i>		
Feminisation acquired	1	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	2	0
Lactation disorder	3	0
Lactation puerperal increased	2	0
Suppressed lactation	9	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	9	0
Premature menopause	4	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	20	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	463	0
Intermenstrual bleeding	248	0
Menstrual discomfort	4	0
Menstrual disorder	391	0
Menstruation irregular	658	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Premenstrual pain	22	0
Premenstrual syndrome	17	0
Withdrawal bleed	2	0
<b><i>Menstruation with decreased bleeding</i></b>		
Amenorrhoea	93	0
Hypomenorrhoea	114	0
Menstruation delayed	797	0
Oligomenorrhoea	30	0
<b><i>Menstruation with increased bleeding</i></b>		
Heavy menstrual bleeding	1044	0
Menometrorrhagia	9	0
Polymenorrhoea	170	0
<b><i>Ovarian and fallopian tube cysts and neoplasms</i></b>		
Ovarian cyst	7	0
Polycystic ovaries	10	0
<b><i>Ovarian and fallopian tube disorders NEC</i></b>		
Fallopian tube spasm	1	0
Ovulation pain	21	0
Premature ovulation	1	0
<b><i>Pelvis and broad ligament disorders NEC</i></b>		
Adnexa uteri pain	19	0
Pelvic haemorrhage	2	0
<b><i>Penile disorders NEC (excl erection and ejaculation)</i></b>		
Penile pain	1	0
Penis disorder	3	0
<b><i>Prostate and seminal vesicles infections and inflammations</i></b>		
Prostatitis	2	0
<b><i>Prostatic signs, symptoms and disorders NEC</i></b>		
Prostatic pain	1	0
<b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>		
Genital blister	1	0
Genital haemorrhage	3	0
Genital paraesthesia	1	0
Genital ulceration	1	0
<b><i>Reproductive tract signs and symptoms NEC</i></b>		
Genital odour	1	0
Genital pain	2	0
Pelvic discomfort	1	0
Pelvic pain	31	0
<b><i>Scrotal disorders NEC</i></b>		
Scrotal pain	8	0
Scrotal swelling	1	0
Varicocele	2	0
<b><i>Sexual function and fertility disorders NEC</i></b>		
Infertility	4	0
Sexual dysfunction	1	0
<b><i>Spermatogenesis and semen disorders</i></b>		
Haemospermia	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular disorder	2	0
Testicular mass	1	0
Testicular pain	21	0
Testicular swelling	5	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b><i>Uterine disorders NEC</i></b>		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	20	0
Metrorrhoea	1	0
Uterine haemorrhage	12	0
Uterine pain	8	0
<b><i>Uterine neoplasms</i></b>		
Uterine polyp	1	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	15	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Vaginal cyst	1	0
Vulva cyst	1	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	328	0
Vaginal ulceration	3	0
Vulval haemorrhage	10	0
Vulval ulceration	2	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	19	0
Vaginal odour	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>4967</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	1	0
Dyspnoea	1506	0
Dyspnoea at rest	1	0
Dyspnoea exertional	6	0
Hyperventilation	14	0
Hypopnoea	30	0
Hypoventilation	1	0
Irregular breathing	6	0
Mouth breathing	1	0
Respiration abnormal	23	0
Respiratory arrest	1	1
Respiratory distress	2	0
Sleep apnoea syndrome	4	0
Tachypnoea	7	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	74	0
Asthma exercise induced	2	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	1	0
Childhood asthma	2	0
Chronic obstructive pulmonary disease	1	0
Obstructive airways disorder	1	0
Wheezing	117	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	3	0
Cough	590	0
Haemoptysis	4	0
Productive cough	37	0
Sputum discoloured	5	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Reflux laryngitis	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonitis	5	0
Pulmonary sarcoidosis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	16	0
Lower respiratory tract congestion	1	0
Pleuritic pain	2	0
Pulmonary haemorrhage	1	0
Pulmonary pain	27	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	65	0
Nasal inflammation	1	0
Rhinitis allergic	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	188	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Nasal dryness	3	0
Nasal oedema	2	0
Nasal pruritus	3	0
<b><i>Paranasal sinus disorders (excl infections and neoplasms)</i></b>		
Sinonasal obstruction	5	0
Sinus congestion	13	0
Sinus disorder	4	0
<b><i>Parenchymal lung disorders NEC</i></b>		
Interstitial lung disease	2	0
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Pharyngeal erythema	2	0
Pharyngeal hypoaesthesia	4	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	62	0
Tonsillar erythema	3	0
Tonsillar hypertrophy	14	0
Tonsillar inflammation	1	0
<b><i>Pleural infections and inflammations</i></b>		
Pleurisy	9	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Pleural effusion	4	0
<b><i>Pulmonary hypertensions</i></b>		
Pulmonary hypertension	1	0
<b><i>Pulmonary oedemas</i></b>		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	5	0
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary embolism	63	1
Pulmonary thrombosis	3	0
<b><i>Respiratory failures (excl neonatal)</i></b>		
Respiratory failure	1	0
<b><i>Respiratory signs and symptoms NEC</i></b>		
Diaphragmalgia	4	0
Painful respiration	4	0
Respiratory symptom	3	0
Use of accessory respiratory muscles	1	0
<b><i>Respiratory tract disorders NEC</i></b>		
Allergic respiratory disease	1	0
Pulmonary mass	1	0
Respiratory disorder	2	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	18	0
Catarrh	5	0
Choking	6	0
Dry throat	28	0
Dysphonia	23	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	8	0
Oropharyngeal blistering	2	0

# Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Oropharyngeal discomfort	3	0
Oropharyngeal pain	560	0
Paranasal sinus discomfort	8	0
Rhinalgia	6	0
Rhinorrhoea	167	0
Sinus pain	73	0
Sneezing	57	0
Throat irritation	42	0
Throat tightness	50	0
Upper-airway cough syndrome	5	0
Yawning	9	0
<b>Respiratory disorders SOC TOTAL</b>	<b>4062</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	37	0
Acne cystic	2	0
Dermatitis acneiform	1	0
<b><i>Alopecias</i></b>		
Alopecia	53	0
Alopecia areata	13	0
Alopecia totalis	2	0
<b><i>Angioedemas</i></b>		
Angioedema	57	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	277	0
Hidradenitis	1	0
Hyperhidrosis	947	0
Miliaria	70	0
Night sweats	305	0
<b><i>Bullous conditions</i></b>		
Blister	91	0
Blister rupture	2	0
Blood blister	3	0
Dermatitis bullous	2	0
Erythema multiforme	15	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<b><i>Connective tissue disorders</i></b>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	101	0
Pain of skin	138	0
Papule	21	0
Scab	5	0
Scar pain	6	0
Sensitive skin	143	0
Skin burning sensation	74	0
Skin discolouration	39	0
Skin discomfort	2	0
Skin disorder	2	0
Skin induration	8	0
Skin lesion	26	0
Skin necrosis	2	0
Skin odour abnormal	3	0
Skin plaque	1	0
Skin reaction	120	0
Skin sensitisation	15	0
Skin swelling	28	0
Skin tightness	7	0
Skin warm	233	0
Skin weeping	2	0
Yellow skin	3	0
<b><i>Dermatitis and eczema</i></b>		



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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Autoimmune dermatitis	1	0
Dermatitis	46	0
Dermatitis allergic	111	0
Dermatitis atopic	16	0
Dermatitis contact	8	0
Dyshidrotic eczema	11	0
Eczema	80	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Flagellate dermatitis	1	0
Hand dermatitis	1	0
Neurodermatitis	1	0
Skin irritation	34	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	4	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	1180	0
Red man syndrome	1	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	19	0
<b><i>Hyperpigmentation disorders</i></b>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<b><i>Hypopigmentation disorders</i></b>		
Skin hypopigmentation	1	0
Vitiligo	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	1	0
Nail ridging	1	0
Onychalgia	1	0
Onychoclasia	1	0
Onychomadesis	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	10	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	4	0
Parapsoriasis	1	0
Pityriasis rosea	16	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	19	0
<b><i>Pigmentation changes NEC</i></b>		
Pigmentation disorder	1	0
<b><i>Pilar disorders NEC</i></b>		
Hair growth abnormal	2	0
Hair texture abnormal	1	0
Piloerection	16	0
Trichodynia	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Pruritus NEC</i></b>		
Itching scar	4	0
Pruritus	2481	0
<b><i>Psoriatic conditions</i></b>		
Guttate psoriasis	2	0
Palmoplantar pustulosis	1	0
Psoriasis	29	0
Rebound psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		
Henoch-Schonlein purpura	1	0
Petechiae	23	0
Purpura	12	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	1	0
Rash	2847	0
Rash erythematous	1080	0
Rash macular	191	0
Rash maculo-papular	5	0
Rash morbilliform	8	0
Rash papular	182	0
Rash pruritic	602	0
Rash vesicular	10	0
<b><i>Rosaceas</i></b>		
Rosacea	2	0
<b><i>Scaly conditions</i></b>		
Pityriasis	4	0
<b><i>Sebaceous gland disorders</i></b>		
Seborrhoea	2	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Cutaneous symptom	4	0
Skin mass	11	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin erosion	5	0
Skin ulcer	6	0
<b><i>Skin cysts and polyps</i></b>		
Dermal cyst	8	0
<b><i>Skin dystrophies</i></b>		
Keloid scar	2	0
Skin wrinkling	1	0
<b><i>Skin haemorrhages</i></b>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	3	0
<b><i>Skin hypoplasias and atrophies</i></b>		
Skin atrophy	3	0
<b><i>Skin injuries and mechanical dermatoses</i></b>		
Needle track marks	2	0
<b><i>Skin vasculitides</i></b>		
Cutaneous vasculitis	3	0
Vasculitic rash	2	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	5	0
<b><i>Telangiectasia and related conditions</i></b>		
Spider naevus	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<i><b>Urticarias</b></i>		
Chronic spontaneous urticaria	3	0
Cold urticaria	1	0
Idiopathic urticaria	4	0
Mechanical urticaria	19	0
Urticaria	655	0
Urticaria aquagenic	1	0
Urticaria cholinergic	2	0
Urticaria chronic	4	0
Urticaria contact	1	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
<b>Skin disorders SOC TOTAL</b>	<b>12704</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menarche	2	0
Menopause	8	0
Postmenopause	2	0
<i>Disability issues</i>		
Bedridden	7	0
Disability	1	0
Immobile	4	0
Impaired driving ability	2	0
Impaired work ability	1	0
Loss of personal independence in daily activities	2	0
Sight disability	2	0
<i>Employment issues</i>		
Retirement	2	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	6	0
<i>Social issues NEC</i>		
Social problem	1	0
<b>Social circumstances SOC TOTAL</b>	<b>42</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	2	0
<i>Contraceptive methods female</i>		
Post coital contraception	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Eye therapeutic procedures NEC</i>		
Eye irrigation	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	3	0
<i>Immunisations</i>		
COVID-19 immunisation	18	0
Immunisation	21	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	3	0
<i>Therapeutic procedures NEC</i>		
Bed rest	4	0
Botulinum toxin injection	1	0
Hospitalisation	3	0
Injection	17	0
Interchange of vaccine products	19	0
Polypectomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>104</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Hypertensive urgency	1	0
<b><i>Arterial infections and inflammations</i></b>		
Giant cell arteritis	3	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	3	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	7	0
Neurogenic shock	1	0
Shock	6	0
<b><i>Haemorrhages NEC</i></b>		
Bloody discharge	2	0
Haematoma	7	0
Haemorrhage	229	0
Internal haemorrhage	3	0
<b><i>Lymphangiopathies</i></b>		
Lymphocele	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	29	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Embolism	3	0
Embolism venous	1	0
Thrombosis	59	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Ischaemia	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Vascular pain	8	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	2	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Axillary vein thrombosis	1	0
Blue toe syndrome	5	0
Deep vein thrombosis	46	0
Pelvic venous thrombosis	2	0
Superficial vein thrombosis	2	0
Thrombophlebitis	5	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	11	0
Erythromelalgia	1	0
Flushing	56	0
Hot flush	303	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		
Extremity necrosis	1	0
Peripheral coldness	104	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	7	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
<i>Site specific vascular disorders NEC</i>		
Pallor	86	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	5	0
Varicose vein ruptured	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	101	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Hypotension	100	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	6	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1232</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>119200</b>	<b>38</b>
<b>TOTAL REPORTS</b>	<b>35810</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>38</b>