

COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 21-Mar-2022
Data Lock Date: 09-Mar-2022 18:30:05
MedDRA Version: MedDRA 24.1

All suspected spontaneous reports from Scotland received up to and including 09/03/2022 for the COVID-19 vaccine Moderna.

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

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	33	0
Lymphadenitis	1	0
Lymphadenopathy	196	0
<i>Neutropenias</i>		
Neutropenia	2	0
<i>Spleen disorders</i>		
Splenic infarction	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	4	0
Blood disorders SOC TOTAL	242	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	154	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	7	0
Myocardial infarction	5	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	17	0
<i>Noninfectious pericarditis</i>		
Pericarditis	12	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	5	0
Bradycardia	1	0
Cardiac flutter	17	0
Extrasystoles	6	0
Tachycardia	63	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	7	0
Atrial flutter	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	1	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Ventricular extrasystoles	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	309	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear discomfort	2	0
Ear disorder	3	0
Ear pain	24	0
<i>Hearing losses</i>		
Deafness	4	0
Hypoacusis	6	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	36	0
Vertigo	18	0
Vertigo positional	2	0
Ear disorders SOC TOTAL	101	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
Ovulation delayed	1	0
<i>Polyglandular endocrine disorders</i>		
Polyglandular disorder	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	1	0
Vitreous floaters	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	4	0
Eyelid ptosis	1	0
<i>Lacrimation disorders</i>		
Dry eye	4	0
Lacrimation increased	4	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye pain	20	0
Eye swelling	8	0
Ocular discomfort	1	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Eye pruritus	1	0
Ocular hyperaemia	4	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	10	0
<i>Pupil disorders</i>		
Mydriasis	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal vein occlusion	2	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Photopsia	3	0
Vision blurred	17	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	4	0
Blindness transient	1	0
Visual impairment	6	0
Eye disorders SOC TOTAL	102	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	2	0
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	1	0
Toothache	4	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	87	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	13	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	10	0
Flatulence	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	29	0
Abdominal pain lower	4	0
Abdominal pain upper	69	0
Abdominal tenderness	2	0
Gastrointestinal pain	4	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal disorders NEC</i>		
Stomach mass	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	13	0
Breath odour	2	0
Dysphagia	3	0
Odynophagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival disorder	1	0
Gingival pain	1	0
Gingival swelling	2	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	4	0
<i>Nausea and vomiting symptoms</i>		
Nausea	383	0
Vomiting	132	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
Upper gastrointestinal haemorrhage	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral dryness and saliva altered</i>		
Dry mouth	6	0
Lip dry	1	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	6	0
Oral pain	6	0
Paraesthesia oral	8	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	15	0
Mouth swelling	3	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Mouth ulceration	10	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Tongue disorder	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	5	0
Swollen tongue	7	0
Gastrointestinal disorders SOC TOTAL	860	0

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site erythema	1	0
Application site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	45	0
Fatigue	518	0
Malaise	71	0
<i>Complications associated with device NEC</i>		
Injury associated with device	1	0
<i>Death and sudden death</i>		
Death	3	3
<i>Febrile disorders</i>		
Pyrexia	587	0
<i>Feelings and sensations NEC</i>		
Chills	315	0
Feeling abnormal	35	0
Feeling cold	22	0
Feeling hot	34	0
Feeling jittery	1	0
Feeling of body temperature change	7	0
Hangover	1	0
Hunger	1	0
Sensation of blood flow	1	0
Sensation of foreign body	2	0
Temperature intolerance	2	0
Thirst	8	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
Gait inability	2	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crying	2	0
Discharge	1	0
Effusion	1	0
Energy increased	1	0
Illness	41	0
Influenza like illness	52	0
Local reaction	1	0
Peripheral swelling	199	0
Screaming	1	0
Swelling	108	0
Swelling face	13	0
<i>Implant and catheter site reactions</i>		
Implant site warmth	1	0
<i>Inflammations</i>		
Inflammation	18	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	2	0
Injection site erythema	17	0
Injection site haemorrhage	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site hypoaesthesia	1	0
Injection site inflammation	2	0
Injection site joint erythema	1	0
Injection site mass	24	0
Injection site oedema	1	0
Injection site pain	88	0
Injection site pruritus	20	0
Injection site rash	22	0
Injection site reaction	4	0
Injection site swelling	10	0
Injection site urticaria	2	0
Injection site warmth	10	0
Mass conditions NEC		
Mass	1	0
Nodule	1	0
Oedema NEC		
Face oedema	1	0
Oedema	3	0
Pain and discomfort NEC		
Axillary pain	65	0
Chest discomfort	57	0
Chest pain	165	0
Discomfort	16	0
Facial pain	3	0
Pain	213	0
Tenderness	21	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	3	0
Drug ineffective	1	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Shoulder injury related to vaccine administration	3	0
Vaccination site discomfort	1	0
Vaccination site erythema	30	0
Vaccination site hypoaesthesia	2	0
Vaccination site induration	1	0
Vaccination site inflammation	1	0
Vaccination site irritation	1	0
Vaccination site mass	9	0
Vaccination site movement impairment	2	0
Vaccination site pain	29	0
Vaccination site pruritus	5	0
Vaccination site rash	12	0
Vaccination site scar	1	0
Vaccination site swelling	18	0
Vaccination site urticaria	2	0
Vaccination site warmth	12	0
General disorders SOC TOTAL	2989	3

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	38	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Drug hypersensitivity	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	5	0
Anaphylactic shock	3	0
<i>Atopic disorders</i>		
Seasonal allergy	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	7	0
Immune system disorders SOC TOTAL	61	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	16	0
Injection site cellulitis	1	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	2	0
<i>Candida infections</i>		
Candida infection	2	0
Oral candidiasis	1	0
Vulvovaginal candidiasis	1	0
<i>Coronavirus infections</i>		
COVID-19	25	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Ear infections</i>		
Labyrinthitis	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		
Hordeolum	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
Fungal skin infection	1	0
<i>Herpes viral infections</i>		
Genital herpes	3	0
Herpes simplex	1	0
Herpes zoster	11	0
Ophthalmic herpes simplex	1	0
Oral herpes	19	0
<i>Infections NEC</i>		
Infection	10	0
Localised infection	2	0
Lymph gland infection	1	0
Lymph node abscess	1	0
Vaccination site infection	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	1	0
<i>Influenza viral infections</i>		
Influenza	51	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	4	1
Pneumonia	1	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Rubella viral infections</i>		
Rubella	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Intestinal sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Impetigo	1	0

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Infections Infections cont'd		
Skin infection	3	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
<i>Tinea infections</i>		
Body tinea	1	0
<i>Upper respiratory tract infections</i>		
Chronic sinusitis	1	0
Nasopharyngitis	20	0
Pharyngitis	1	0
Rhinitis	1	0
Sinusitis	1	0
Tonsillitis	3	0
<i>Urinary tract infections</i>		
Urinary tract infection	4	0
<i>Vascular infections</i>		
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Sweating fever	5	0
Viral rash	1	0
Infections SOC TOTAL	211	1

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Reaction Name	Total	Fatal
Injuries		
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Cerebral injuries NEC</i>		
Concussion	2	0
Subdural haematoma	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	2	0
<i>Conditions caused by cold</i>		
Chillblains	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	2	0
Maternal exposure during breast feeding	72	0
Maternal exposure during pregnancy	25	0
<i>Eye injuries NEC</i>		
Eye injury	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	1	0
Heat stroke	1	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	2	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
Struck by lightning	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
<i>Radiation injuries</i>		
Sunburn	1	0
<i>Site specific injuries NEC</i>		
Back injury	2	0
Head injury	1	0
Limb injury	6	0
<i>Skin injuries NEC</i>		
Contusion	24	0
Scratch	1	0
<i>Thermal burns</i>		
Thermal burn	1	0
Injuries SOC TOTAL	157	0

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Investigations		
Adrenal medulla tests		
Norepinephrine increased	1	0
Bacteria identification and serology (excl mycobacteria)		
Campylobacter test positive	1	0
Blood gas and acid base analyses		
Oxygen saturation decreased	1	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose increased	1	0
Coagulation and bleeding analyses		
Coagulation time shortened	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	1	0
Gastrointestinal and abdominal imaging procedures		
X-ray with contrast upper gastrointestinal tract	1	0
Haematological analyses NEC		
Blood viscosity increased	1	0
Heart rate and pulse investigations		
Heart rate	21	0
Heart rate abnormal	2	0
Heart rate decreased	2	0
Heart rate increased	36	0
Heart rate irregular	10	0
Heart rate variability decreased	1	0
Investigations NEC		
Blood test	1	0
Liver function analyses		
Bile output	1	0
Liver function test abnormal	2	0
Mineral and electrolyte analyses		
Blood potassium decreased	1	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone scan	1	0
Physical examination procedures and organ system status		
Body temperature	3	0
Body temperature abnormal	1	0
Body temperature fluctuation	3	0
Body temperature increased	9	0
Lymph node palpable	1	0
Respiratory rate	1	0
Respiratory rate decreased	2	0
Skin temperature	2	0
Temperature difference of extremities	1	0
Weight decreased	3	0
Platelet analyses		
Platelet count decreased	1	0
Protein analyses NEC		
C-reactive protein increased	3	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Therapeutic drug monitoring analyses		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Analgesic drug level	1	0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase increased	1	0
Urinalysis NEC		
Blood urine present	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure increased	3	0
Blood pressure measurement	1	0
Virus identification and serology		
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	1	0
Vitamin analyses		
Blood folate decreased	1	0
Investigations SOC TOTAL	131	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	44	0
Food refusal	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Feeding disorder	2	0
Neonatal insufficient breast milk syndrome	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Iron excess</i>		
Haemochromatosis	1	0
<i>Total fluid volume decreased</i>		
Dehydration	10	0
Metabolic disorders SOC TOTAL	63	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	9	0
Arthropathy	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	11	0
Pain in jaw	7	0
<i>Bursal disorders</i>		
Bursitis	4	0
<i>Cartilage disorders</i>		
Costochondritis	2	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	6	0
<i>Joint related signs and symptoms</i>		
Arthralgia	212	0
Joint noise	1	0
Joint stiffness	6	0
Joint swelling	6	0
<i>Muscle pains</i>		
Fibromyalgia	3	0
Myalgia	280	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	11	0
Muscle spasms	41	0
Muscle swelling	1	0
Muscle tightness	4	0
Muscle twitching	13	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	24	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Mobility decreased	2	0
Muscle contracture	1	0
Musculoskeletal stiffness	40	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	75	0
Flank pain	1	0
Limb discomfort	36	0
Musculoskeletal chest pain	9	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	4	0
Neck pain	50	0
Pain in extremity	326	0
Sacral pain	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0

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Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Soft tissue disorders NEC</i>		
Axillary mass	4	0
Groin pain	5	0
Neck mass	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	4	0
<i>Tendon disorders</i>		
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	1214	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Skin neoplasms benign</i>		
Acrochordon	1	0
Haemangioma of skin	1	0
Skin papilloma	1	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	1	0
Neoplasms SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	2	0
Haemorrhagic stroke	1	0
Ischaemic stroke	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	4	0
Dysstasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	2	0
Lethargy	28	0
Loss of consciousness	21	0
Somnolence	10	0
Syncope	59	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	14	0
Facial paralysis	7	0
Facial spasm	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Cluster headache	4	0
Headache	627	0
New daily persistent headache	1	0
Sinus headache	4	0
Tension headache	15	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	2	0
<i>Memory loss (excl dementia)</i>		
Amnesia	5	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	8	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	80	0
Migraine with aura	3	0
Retinal migraine	2	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	2	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	220	0
Dizziness postural	17	0
Head discomfort	5	0
Persistent postural-perceptual dizziness	1	0
Presyncope	7	0
Unresponsive to stimuli	1	0
<i>Neuromuscular disorders NEC</i>		
Neuromuscular pain	1	0
<i>Olfactory nerve disorders</i>		
Anosmia	3	0
Parosmia	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	1	0
Burning sensation	11	0
Hemianaesthesia	1	0
Hyperaesthesia	8	0
Hypoaesthesia	65	0
Paraesthesia	71	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Monoparesis	4	0
Monoplegia	1	0
Paralysis	2	0
Paresis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	3	0
Febrile convulsion	1	0
Partial seizures	1	0
Seizure	18	0
Status epilepticus	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	10	0
Allodynia	1	0
Aura	1	0
Dysgeusia	23	0
Neuralgia	14	0
Restless legs syndrome	4	0
Sensory loss	4	0
Taste disorder	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	2	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Speech disorder	2	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	3	0
<i>Tremor (excl congenital)</i>		
Tremor	50	0
Nervous system disorders SOC TOTAL	1485	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	7	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	10	0

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Reaction Name	Total	Fatal
<i>Device malfunction events NEC</i>		
Oversensing	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	1	0
null SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Affect alterations NEC</i>		
Flat affect	1	0
<i>Amnesic symptoms</i>		
Paramnesia	1	0
<i>Anxiety symptoms</i>		
Agitation	3	0
Anxiety	23	0
Nervousness	2	0
Stress	3	0
Tension	1	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	7	0
<i>Confusion and disorientation</i>		
Confusional state	14	0
Disorientation	6	0
<i>Deliria</i>		
Delirium	2	0
<i>Depressive disorders</i>		
Depression	6	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	45	0
Middle insomnia	1	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	10	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	3	0
Irritability	6	0
Mood altered	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	6	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	10	0
<i>Increased physical activity levels</i>		
Restlessness	3	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	12	0
Feeling of despair	1	0
<i>Mood disorders NEC</i>		
Affective disorder	1	0
Apathy	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Dermatophagia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Orgasmic disorders and disturbances</i>		
Orgasmic sensation decreased	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Paraphilias and paraphilic disorders</i>		
Exhibitionism	1	0
<i>Parasomnias</i>		
Abnormal dreams	6	0
Nightmare	10	0
Sleep terror	1	0
<i>Perception disturbances NEC</i>		
Derealisation	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Sexual desire disorders</i>		
Libido decreased	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	9	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
Habit cough	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Stereotypies and automatisms</i>		
Head banging	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	1	0
Thought blocking	1	0
Psychiatric disorders SOC TOTAL	218	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	2	0
Pollakiuria	3	0
Urinary incontinence	2	0
<i>Bladder disorders NEC</i>		
Urinary bladder haemorrhage	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Haematuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	2	0
Renal pain	14	0
Renal & urinary disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast enlargement	2	0
Breast mass	1	0
<i>Breast signs and symptoms</i>		
Breast pain	13	0
Breast swelling	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
Painful ejaculation	1	0
<i>Lactation disorders</i>		
Suppressed lactation	1	0
<i>Menopausal effects NEC</i>		
Premature menopause	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	4	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	60	0
Intermenstrual bleeding	32	0
Menstrual disorder	48	0
Menstruation irregular	74	0
Premenstrual dysphoric disorder	1	0
Premenstrual pain	3	0
Premenstrual syndrome	3	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	10	0
Hypomenorrhoea	10	0
Menstruation delayed	114	0
Oligomenorrhoea	5	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	108	0
Menometrorrhagia	2	0
Polymenorrhoea	16	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital blister	1	0
Genital haemorrhage	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	9	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	3	0
Testicular swelling	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	5	0
<i>Uterine tone disorders</i>		
Uterine spasm	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	39	0
Vulval haemorrhage	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	2	0
Reproductive & breast disorders SOC TOTAL	581	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	129	0
Hyperventilation	1	0
Hypopnoea	2	0
Respiration abnormal	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Wheezing	10	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	56	0
Productive cough	5	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	3	0
Lower respiratory tract congestion	1	0
Pulmonary pain	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	6	0
<i>Nasal disorders NEC</i>		
Epistaxis	21	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal swelling	5	0
<i>Pleural infections and inflammations</i>		
Pleurisy	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	8	0
<i>Respiratory signs and symptoms NEC</i>		
Respiratory symptom	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Catarrh	1	0
Dry throat	6	0
Dysphonia	1	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	54	0
Paranasal sinus discomfort	2	0
Rhinorrhoea	18	0
Sinus pain	10	0
Sneezing	8	0
Throat irritation	2	0
Throat tightness	5	0
Yawning	2	0
Respiratory disorders SOC TOTAL	375	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	6	0
Acne cystic	1	0
<i>Alopecias</i>		
Alopecia	7	0
<i>Angioedemas</i>		
Angioedema	8	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	16	0
Hyperhidrosis	91	0
Miliaria	7	0
Night sweats	25	0
<i>Bullous conditions</i>		
Blister	7	0
Dermatitis bullous	1	0
Erythema multiforme	3	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	12	0
Pain of skin	14	0
Papule	3	0
Scar pain	1	0
Sensitive skin	14	0
Skin burning sensation	5	0
Skin discolouration	2	0
Skin disorder	1	0
Skin lesion	3	0
Skin odour abnormal	1	0
Skin reaction	15	0
Skin swelling	3	0
Skin warm	16	0
<i>Dermatitis and eczema</i>		
Dermatitis	5	0
Dermatitis allergic	18	0
Dermatitis atopic	2	0
Dermatitis contact	1	0
Dyshidrotic eczema	2	0
Eczema	9	0
Skin irritation	6	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	117	0
<i>Exfoliative conditions</i>		
Exfoliative rash	1	0
Skin exfoliation	1	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
<i>Panniculitides</i>		
Erythema nodosum	2	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	3	0
<i>Photosensitivity and photodermatitis conditions</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Photosensitivity reaction	2	0
Pigmentation changes NEC		
Pigmentation disorder	1	0
Pilar disorders NEC		
Piloerection	3	0
Pruritus NEC		
Pruritus	255	0
Psoriatic conditions		
Guttate psoriasis	1	0
Psoriasis	1	0
Rebound psoriasis	1	0
Purpura and related conditions		
Purpura	1	0
Rashes, eruptions and exanthems NEC		
Rash	307	0
Rash erythematous	113	0
Rash macular	20	0
Rash morbilliform	1	0
Rash papular	22	0
Rash pruritic	80	0
Rash vesicular	2	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	2	0
Skin mass	2	0
Skin dystrophies		
Keloid scar	1	0
Urticarias		
Cold urticaria	1	0
Mechanical urticaria	4	0
Urticaria	58	0
Urticaria aquagenic	1	0
Skin disorders SOC TOTAL	1311	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	1	0
Social circumstances SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
Immunisation	2	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Injection	3	0
Surgical & medical procedures SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	28	0
<i>Lymphoedemas</i>		
Lymphoedema	2	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	7	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Infarction	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	4	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	7	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	4	0
Hot flush	28	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	10	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	4	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	5	0
<i>Vascular hypotensive disorders</i>		
Hypotension	3	0
Vascular disorders SOC TOTAL	110	0
TOTAL REACTIONS FOR DRUG	10585	4
TOTAL REPORTS	3158	
TOTAL FATAL OUTCOME REPORTS		4