

Case Series Drug Analysis Print

Name: FOI 21/877 Inactivated Influenza Vaccine DAP 2019

Report Run Date: 09-Aug-2021

Data Lock Date: 08-Aug-2021 18:30:04

Earliest Reaction Date: 01-Jul-2004

MedDRA Version: MedDRA 24.0

FOI 21/877 Influenza All spontaneous suspected UK Adverse Drug Reaction
inactivated Vaccine (ADR) reports associated with the Inactivated Influenza
DAP 2019: Virus Vaccine in 2019

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
Anaemia macrocytic	1	0
<i>Leukocytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	2	0
Lymphadenopathy	25	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	1
Blood disorders SOC TOTAL	33	1

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	15	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Extrasystoles	3	0
Tachycardia	6	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	4	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	36	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i>		
Branchial cyst	1	0
Congenital disorders SOC TOTAL	1	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 pain	5	0
Ear pruritus	1	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness unilateral	1	0
Hypoacusis	3	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Meniere's disease	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	10	0
Ear disorders SOC TOTAL	34	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Endocrine disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis allergic	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	2	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
Lacrimation increased	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Chalazion	1	0
Swelling of eyelid	4	0
<i>Ocular disorders NEC</i>		
Eye pain	6	0
Eye swelling	4	0
Eyelid disorder	1	0
Periorbital swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye irritation	2	0
Ocular hyperaemia	3	0
<i>Ocular sensation disorders</i>		
Foreign body sensation in eyes	1	0
Photophobia	5	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness unilateral	1	0
Visual impairment	5	0
Eye disorders SOC TOTAL	48	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis microscopic	1	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	75	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
Eructation	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
Flatulence	3	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	8	0
Abdominal pain lower	1	0
Abdominal pain upper	16	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	5	0
Dysphagia	8	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Nausea and vomiting symptoms</i>		
Acetonaemic vomiting	1	0
Nausea	105	0
Retching	1	0
Vomiting	71	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	3	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Lip blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	2	0
Lip erythema	1	0
Lip pain	1	0
Oral discomfort	1	0
Oral mucosal eruption	1	0
Paraesthesia oral	17	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Mouth swelling	4	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Apthous ulcer	1	0
Mouth ulceration	4	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Glossitis	1	0
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	3	0
Swollen tongue	8	0
Tongue discolouration	1	0
Tongue eruption	1	0
Gastrointestinal disorders SOC TOTAL	372	0

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site vesicles	1	0
<i>Asthenic conditions</i>		
Asthenia	30	0
Fatigue	101	0
Malaise	115	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	1	0
<i>Death and sudden death</i>		
Brain death	1	1
Death	5	5
Sudden cardiac death	1	0
<i>Febrile disorders</i>		
Pyrexia	131	0
<i>Feelings and sensations NEC</i>		
Chills	62	0
Feeling abnormal	12	0
Feeling cold	18	0
Feeling drunk	1	0
Feeling hot	29	0
Feeling of body temperature change	2	0
Sensation of foreign body	1	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	9	0
Glassy eyes	1	0
Illness	9	0
Induration	4	0
Influenza like illness	52	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	40	0
Swelling	27	0
Swelling face	20	0
<i>Hernias NEC</i>		
Hernia	1	0
<i>Inflammations</i>		
Inflammation	10	0
<i>Injection site reactions</i>		
Injection site bruising	1	0
Injection site erythema	23	0
Injection site haemorrhage	1	0
Injection site hypoaesthesia	1	0
Injection site inflammation	3	0
Injection site pain	16	0
Injection site paraesthesia	1	0
Injection site pruritus	9	0
Injection site rash	1	0
Injection site swelling	6	0
Injection site vesicles	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site warmth	6	0
Interactions		
Drug interaction	3	0
Mass conditions NEC		
Mass	2	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Oedema	1	0
Pain and discomfort NEC		
Axillary pain	6	0
Chest discomfort	12	0
Chest pain	10	0
Discomfort	5	0
Facial pain	1	0
Pain	88	0
Tenderness	5	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Therapeutic response unexpected	1	0
Vaccination failure	5	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	2	0
Vaccination site bruising	8	0
Vaccination site coldness	1	0
Vaccination site discharge	1	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site erythema	68	0
Vaccination site hypersensitivity	1	0
Vaccination site induration	9	0
Vaccination site inflammation	14	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	1	0
Vaccination site mass	22	0
Vaccination site movement impairment	9	0
Vaccination site pain	82	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	18	0
Vaccination site rash	11	0
Vaccination site reaction	6	0
Vaccination site scab	1	0
Vaccination site swelling	75	0
Vaccination site urticaria	1	0
Vaccination site vesicles	4	0
Vaccination site warmth	34	0
General disorders SOC TOTAL	1279	6

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	1	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	17	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
Food allergy	1	0
Reaction to excipient	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	16	0
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	2	0
<i>Vasculitides</i>		
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	0
Immune system disorders SOC TOTAL	54	1

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diverticulitis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	11	0
Vaccination site cellulitis	2	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
<i>Ear infections</i>		
Labyrinthitis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
Eye infection	1	0
Hordeolum	1	0
<i>Fungal infections NEC</i>		
Ear infection fungal	1	0
<i>Hepatobiliary and spleen infections</i>		
Liver abscess	1	0
<i>Herpes viral infections</i>		
Genital herpes	1	0
Herpes simplex reactivation	1	0
Herpes zoster	7	0
Oral herpes	4	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	2	0
Injection site abscess	1	0
Localised infection	2	0
<i>Infectious transmissions</i>		
Infection via vaccinee	2	0
Vaccine virus shedding	2	0
<i>Influenza viral infections</i>		
Influenza	35	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	10	0
Pneumonia	5	1
<i>Pseudomonal infections</i>		
Pseudomonas infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	0
Septic shock	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Vaccination site pustule	1	0
<i>Streptococcal infections</i>		
Pneumonia pneumococcal	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	14	0
Pharyngitis	2	0
Rhinitis	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Sinusitis	2	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Urinary tract infection	1	0
<i>Vascular infections</i>		
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	3	0
Viral labyrinthitis	1	0
Infections SOC TOTAL	133	1

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Brain herniation	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure during pregnancy	7	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
<i>Product administration errors and issues</i>		
Contraindicated product administered	1	0
Extra dose administered	2	0
Inappropriate schedule of product administration	1	0
Product administered at inappropriate site	5	0
Product administered to patient of inappropriate age	2	0
Product dose omission issue	1	0
<i>Skin injuries NEC</i>		
Contusion	6	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	34	0

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Anti-glomerular basement membrane antibody positive	1	0
Antineutrophil cytoplasmic antibody positive	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose increased	1	0
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging head abnormal	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio increased	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	13	0
Pulse abnormal	1	0
<i>Imaging procedures NEC</i>		
Computerised tomogram abnormal	1	0
Ultrasound scan abnormal	1	0
<i>Immune response protein analyses NEC</i>		
Complement factor C3 increased	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
Gamma-glutamyltransferase increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood phosphorus increased	1	0
Blood potassium decreased	1	0
Blood sodium decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	7	0
Breath sounds abnormal	1	0
Respiratory rate increased	3	0
Weight decreased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
Platelet count increased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein	1	0
C-reactive protein increased	2	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
Blood urea increased	1	0
Glomerular filtration rate decreased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate decreased	1	0
Pulmonary function test decreased	1	0
Total lung capacity decreased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Skeletal and cardiac muscle analyses</i>		
Troponin increased	1	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	2	0
Protein urine present	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Urinary tract histopathology procedures</i>		
Biopsy kidney abnormal	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	2	0
Blood pressure increased	2	0
<i>White blood cell analyses</i>		
Neutrophil count increased	1	0
White blood cell count increased	3	0
Investigations SOC TOTAL	72	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	28	0
Salt craving	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	5	0
Feeding disorder	3	0
Food aversion	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
Metabolic disorders SOC TOTAL	42	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	8	0
Arthropathy	1	0
Seronegative arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	5	0
Pain in jaw	1	0
<i>Bursal disorders</i>		
Bursitis	19	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	5	0
<i>Extremity deformities</i>		
Hand deformity	1	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
Periarthritis	5	0
<i>Joint related signs and symptoms</i>		
Arthralgia	91	0
Joint effusion	1	0
Joint noise	2	0
Joint stiffness	5	0
Joint swelling	7	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Myalgia	94	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle fatigue	2	0
Muscle spasms	14	0
Muscle swelling	1	0
Muscle tightness	2	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
Torticollis	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	27	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	30	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	21	0
Flank pain	1	0
Limb discomfort	10	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	14	0
Pain in extremity	91	0

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Muscle & tissue disorders Muscle & tissue disorders cont'd		
<i>Osteoarthropathies</i>		
Osteoarthritis	3	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	4	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Groin pain	1	0
Neck mass	2	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
<i>Tendon disorders</i>		
Tendon pain	2	0
Muscle & tissue disorders SOC TOTAL	486	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leiomyosarcomas</i>		
Leiomyosarcoma	1	0
Neoplasms SOC TOTAL	1	0

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Earliest Reaction Date: 01-Jul-2004

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	3	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	16	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebellar stroke	1	0
Cerebral haemorrhage	1	0
Cerebral infarction	1	0
Cerebrovascular accident	2	1
Ischaemic stroke	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	10	0
Coordination abnormal	2	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	32	0
Loss of consciousness	13	0
Somnolence	14	0
Syncope	26	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	3	0
Hypokinesia	1	0
Movement disorder	3	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	3	0
Facial paralysis	2	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Headache	151	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	2	0
<i>Migraine headaches</i>		

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Migraine	12	0
Multiple sclerosis acute and progressive		
Multiple sclerosis relapse	1	0
Muscle tone abnormal		
Hypotonia	1	0
Myelitis (incl infective)		
Myelitis transverse	2	0
Neurologic visual problems NEC		
Tunnel vision	1	0
Neurological signs and symptoms NEC		
Dizziness	81	0
Dizziness postural	3	0
Drooling	1	0
Head discomfort	1	0
Neurological symptom	2	0
Presyncope	8	0
Unresponsive to stimuli	1	0
Optic nerve disorders NEC		
Optic neuritis	1	0
Paraesthesias and dysaesthesias		
Burning sensation	8	0
Formication	1	0
Hyperaesthesia	1	0
Hypoaesthesia	24	0
Paraesthesia	36	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	1	0
Paralysis	1	0
Quadriparesis	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Polyneuropathy	1	0
Seizures and seizure disorders NEC		
Epilepsy	2	0
Seizure	2	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Dysgeusia	9	0
Neuralgia	8	0
Sensory disturbance	6	0
Sensory loss	3	0
Taste disorder	4	0
Speech and language abnormalities		
Dysarthria	3	0
Incoherent	2	0
Repetitive speech	1	0
Speech disorder	3	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	1	0
Tremor (excl congenital)		
Tremor	14	0
Vagus nerve disorders		
Vocal cord paralysis	1	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Nervous system disorders SOC TOTAL	553	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<i>Normal pregnancy, labour and delivery</i>		
Uterine contractions during pregnancy	1	0
Pregnancy conditions SOC TOTAL	4	0

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Reaction Name	Total	Fatal
<i>Device malfunction events NEC</i>		
Device malfunction	1	0
Oversensing	1	0
<i>Product supply and availability issues</i>		
Product supply issue	1	0
null SOC TOTAL	3	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>		
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	6	0
Nervousness	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	13	0
Disorientation	2	0
<i>Decreased physical activity levels</i>		
Catatonia	2	0
<i>Depressive disorders</i>		
Depression	6	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	7	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
Feeling of despair	1	0
Negative thoughts	1	0
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	2	0
<i>Parasomnias</i>		
Nightmare	2	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	2	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	1	0
<i>Stereotypies and automatisms</i>		
Automatism	1	0
Echolalia	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
<i>Thinking disturbances</i>		
Thinking abnormal	1	0
Psychiatric disorders SOC TOTAL	62	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder spasm	1	0
Pollakiuria	1	0
Urinary retention	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	1	0
Nephrotic syndrome	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	5	0
Chronic kidney disease	1	0
Renal impairment	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal tubular injury	1	0
<i>Urethral infections and inflammations</i>		
Urethritis noninfective	1	0
<i>Urinary abnormalities</i>		
Haematuria	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal disorder	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	2	0
Reproductive & breast disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	41	0
Hypopnoea	1	0
Irregular breathing	1	0
Respiration abnormal	2	0
Respiratory arrest	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	4	0
Chronic obstructive pulmonary disease	2	0
Wheezing	13	0
<i>Coughing and associated symptoms</i>		
Cough	32	0
Productive cough	12	0
Sputum increased	2	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonia aspiration	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	12	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	3	0
Sinus disorder	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	11	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pneumothorax	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	1
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	3	0
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	2	0
Catarrh	2	0
Choking	1	0
Dry throat	1	0
Dysphonia	6	0
Nasal discomfort	1	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	30	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	21	0
Sinus pain	4	0
Sneezing	9	0
Throat irritation	2	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Throat tightness	10	0
Upper-airway cough syndrome	3	0
Respiratory disorders SOC TOTAL	247	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia areata	1	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	13	0
Hyperhidrosis	48	0
Miliaria	1	0
Night sweats	5	0
<i>Bullous conditions</i>		
Blister	5	0
Blood blister	1	0
Erythema multiforme	1	0
<i>Connective tissue disorders</i>		
Dermatomyositis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Pain of skin	4	0
Papule	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin discolouration	3	0
Skin reaction	2	0
Skin texture abnormal	2	0
Skin warm	9	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	8	0
Eczema	2	0
Skin irritation	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	53	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Pilar disorders NEC</i>		
Piloerection	1	0
<i>Pruritus NEC</i>		
Pruritus	60	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	5	0
Petechiae	1	0
Purpura	6	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	47	0
Rash erythematous	11	0
Rash macular	9	0
Rash maculo-papular	5	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash papular	4	0
Rash pruritic	6	0
Rash vesicular	2	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
Subcutaneous emphysema	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	1	0
Palpable purpura	2	0
Vasculitic rash	3	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	28	0
Skin disorders SOC TOTAL	365	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Impaired work ability	1	0
Loss of personal independence in daily activities	3	0
Social circumstances SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	2	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	4	0
Shock	2	0
<i>Non-site specific vascular disorders NEC</i>		
Vein disorder	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	7	0
Hot flush	5	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Ischaemic limb pain	1	0
Peripheral coldness	2	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	9	0
<i>Varicose veins NEC</i>		
Varicose vein	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	6	0
<i>Vascular hypotensive disorders</i>		
Hypotension	6	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Vasculitis	2	0
Vascular disorders SOC TOTAL	52	0
TOTAL REACTIONS FOR DRUG	3948	11
TOTAL REPORTS	1145	
TOTAL FATAL OUTCOME REPORTS		11