

## Case Series Drug Analysis Print

**Name: FOI 21/877 Inactivated Influenza Vaccine DAP 2018**

Report Run Date: 09-Aug-2021

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

Earliest Reaction Date: 16-Nov-2007

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 2018: Virus Vaccine in 2018

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemias NEC</b></i>		
Anaemia	1	0
<i><b>Leukocytoses NEC</b></i>		
Neutrophilia	1	0
<i><b>Leukopenias NEC</b></i>		
Lymphopenia	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	4	0
Lymphadenopathy	20	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Aplastic anaemia	2	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	2	0
<b>Blood disorders SOC TOTAL</b>	<b>32</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Cardiovascular disorder	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	23	0
<i><b>Cardiomyopathies</b></i>		
Stress cardiomyopathy	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure acute	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	1	0
Acute myocardial infarction	1	0
Angina pectoris	1	0
<i><b>Myocardial disorders NEC</b></i>		
Left ventricular dysfunction	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	3	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	5	0
Tachycardia paroxysmal	1	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	4	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>45</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cerebral disorders congenital</i>		
Dandy-Walker syndrome	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>External ear disorders congenital</i>		
Accessory auricle	1	0
Low set ears	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Hemivertebra	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear congestion	3	0
Ear discomfort	4	0
Ear pain	6	0
Ear swelling	2	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness unilateral	5	0
Sudden hearing loss	2	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	2	0
Tinnitus	7	0
Vertigo	10	0
<b>Ear disorders SOC TOTAL</b>	<b>43</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Glaucomas (excl congenital)</b></i>		
Glaucoma	1	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Uveitis	1	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	1	0
Lacrimal disorder	1	0
Lacrimation increased	3	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Eyelid irritation	1	0
Swelling of eyelid	1	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Eyelid thickening	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye pain	13	0
Eye swelling	8	0
Eyelid pain	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye discharge	2	0
Eye irritation	2	0
Ocular hyperaemia	3	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	2	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	1	0
Photophobia	3	0
<i><b>Optic nerve bleeding and vascular disorders</b></i>		
Optic ischaemic neuropathy	1	0
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
<i><b>Retinal, choroid and vitreous infections and inflammations</b></i>		
Cystoid macular oedema	1	0
<i><b>Retinopathies NEC</b></i>		
Acute macular outer retinopathy	1	0
<i><b>Structural change, deposit and degeneration of eye NEC</b></i>		
Exophthalmos	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	1	0
Photopsia	1	0
Vision blurred	7	0
<i><b>Visual field disorders</b></i>		
Visual field defect	1	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	1	0
Blindness transient	1	0
Visual impairment	6	0
<b>Eye disorders SOC TOTAL</b>	<b>69</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	3	0
Pancreatitis acute	3	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	71	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	4	0
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	11	0
Abdominal pain lower	1	0
Abdominal pain upper	28	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	5	0
Dysphagia	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Irritable bowel syndrome	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoidal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	127	0
Retching	1	0
Vomiting	69	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	3	0
Lip dry	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Oral lichen planus	2	0
<i>Oral soft tissue signs and symptoms</i>		
Lip pain	1	0
Oral discomfort	1	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	1	0
Paraesthesia oral	9	0



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b> Gastrointestinal disorders cont'd		
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	14	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	2	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	9	0
Tongue discomfort	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>392</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 joint pain	1	0
Administration site rash	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site reaction	1	0
<b><i>Asthenic conditions</i></b>		
Asthenia	36	0
Fatigue	127	0
Malaise	138	0
<b><i>Death and sudden death</i></b>		
Death	2	2
<b><i>Febrile disorders</i></b>		
Pyrexia	119	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	81	0
Feeling abnormal	9	0
Feeling cold	18	0
Feeling hot	35	0
Feeling of body temperature change	11	0
Sensation of foreign body	2	0
Thirst	3	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	6	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	6	0
Crying	1	0
Effusion	1	0
General physical health deterioration	1	0
Illness	11	0
Induration	7	0
Influenza like illness	69	0
Local reaction	5	0
Moaning	1	0
Peripheral swelling	45	0
Swelling	38	0
Swelling face	14	0
<b><i>Inflammations</i></b>		
Inflammation	15	0
Soft tissue inflammation	1	0
<b><i>Injection site reactions</i></b>		
Injected limb mobility decreased	3	0
Injection site erythema	6	0
Injection site haemorrhage	2	0
Injection site pain	14	0
Injection site pruritus	5	0
Injection site reaction	1	0
Injection site swelling	1	0
Injection site warmth	2	0
<b><i>Interactions</i></b>		
Alcohol interaction	1	0
Drug interaction	4	0
<b><i>Mass conditions NEC</i></b>		
Mass	2	0

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<b>General disorders</b> General disorders cont'd		
<b><i>Oedema NEC</i></b>		
Localised oedema	1	0
Oedema	1	0
Oedema peripheral	2	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	1	0
Chest discomfort	6	0
Chest pain	8	0
Discomfort	6	0
Facial pain	5	0
Pain	99	0
Tenderness	5	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse event	1	0
Immediate post-injection reaction	1	0
Vaccination failure	3	0
<b><i>Vaccination site reactions</i></b>		
Shoulder injury related to vaccine administration	2	0
Vaccination site atrophy	1	0
Vaccination site bruising	23	0
Vaccination site discolouration	3	0
Vaccination site discomfort	9	0
Vaccination site eczema	1	0
Vaccination site erythema	137	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	1	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	29	0
Vaccination site inflammation	24	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	2	0
Vaccination site joint swelling	1	0
Vaccination site mass	19	0
Vaccination site movement impairment	14	0
Vaccination site pain	142	0
Vaccination site papule	1	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	33	0
Vaccination site rash	15	0
Vaccination site reaction	1	0
Vaccination site swelling	122	0
Vaccination site urticaria	2	0
Vaccination site vesicles	3	0
Vaccination site warmth	58	0
<b>General disorders SOC TOTAL</b>	<b>1638</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	1
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatic cytolysis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>3</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	33	0
Type IV hypersensitivity reaction	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	21	0
Anaphylactic shock	1	0
Anaphylactoid reaction	3	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	1	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	1	0
<i><b>Immunodeficiency disorders NEC</b></i>		
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>63</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Diverticulitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Administration site cellulitis	1	0
Cellulitis	7	0
Vaccination site cellulitis	7	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	2	0
<b><i>Ear infections</i></b>		
Ear infection	1	0
Labyrinthitis	2	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	1	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	5	0
Ophthalmic herpes zoster	1	0
Oral herpes	5	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Abscess limb	1	0
Infection	1	0
Injection site infection	1	0
Purulence	1	0
Vaccination site infection	4	0
<b><i>Influenza viral infections</i></b>		
Influenza	23	1
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	8	0
Pneumonia	7	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	2	0
Urosepsis	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Skin infection	1	0
<b><i>Upper respiratory tract infections</i></b>		
Laryngitis	1	0
Nasopharyngitis	25	0
Pharyngitis	3	0
Rhinitis	1	0
Sinusitis	1	0
Tonsillitis	1	0
<b><i>Urinary tract infections</i></b>		
Cystitis	1	0
Urinary tract infection	1	0
<b><i>Viral infections NEC</i></b>		
Vestibular neuronitis	1	0
Viral infection	1	0
Viral labyrinthitis	1	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>122</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	1	0
Maternal exposure during pregnancy	6	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Product use issue	1	0
Wrong technique in product usage process	1	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Tendon rupture	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	2	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	1	0
<i><b>Poisoning and toxicity</b></i>		
Alcohol poisoning	1	0
Toxicity to various agents	1	0
<i><b>Product administration errors and issues</b></i>		
Extra dose administered	1	0
Product administered at inappropriate site	6	0
Product administration error	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	12	0
Scar	1	0
<b>Injuries SOC TOTAL</b>	<b>36</b>	<b>0</b>

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<b>Investigations</b>		
<i><b>Blood counts NEC</b></i>		
Blood count abnormal	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Carbon dioxide decreased	1	0
Oxygen saturation decreased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose increased	2	0
<i><b>Coagulation and bleeding analyses</b></i>		
International normalised ratio increased	2	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	4	0
Heart rate increased	6	0
Heart rate irregular	5	0
<i><b>Imaging procedures NEC</b></i>		
Computerised tomogram abnormal	1	0
Optical coherence tomography abnormal	1	0
Ultrasound scan abnormal	1	0
<i><b>Investigations NEC</b></i>		
Blood test abnormal	2	0
<i><b>Liver function analyses</b></i>		
Liver function test abnormal	2	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood calcium increased	1	0
Blood sodium decreased	1	0
<i><b>Musculoskeletal and soft tissue imaging procedures</b></i>		
Spinal X-ray abnormal	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	1	0
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	8	0
Grip strength decreased	3	0
Weight decreased	1	0
Weight increased	2	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Vital capacity decreased	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	1	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output decreased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	2	0
Blood pressure increased	4	0
<i><b>Virus identification and serology</b></i>		
Influenza A virus test positive	1	0
<i><b>White blood cell analyses</b></i>		
Lymphocyte count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>62</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	30	0
Hypophagia	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	1	0
Feeding disorder	2	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	2	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>41</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	7	0
Seronegative arthritis	1	0
<b><i>Bone disorders NEC</i></b>		
Exostosis	1	0
Jaw disorder	1	0
<b><i>Bone related signs and symptoms</i></b>		
Pain in jaw	2	0
<b><i>Bursal disorders</i></b>		
Bursitis	3	0
<b><i>Connective tissue disorders NEC</i></b>		
Polymyalgia rheumatica	4	0
<b><i>Intervertebral disc disorders NEC</i></b>		
Intervertebral disc space narrowing	1	0
<b><i>Joint related disorders NEC</i></b>		
Periarthritis	9	0
Rotator cuff syndrome	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	99	0
Joint noise	1	0
Joint stiffness	5	0
Joint swelling	6	0
<b><i>Muscle infections and inflammations</i></b>		
Myositis	4	0
<b><i>Muscle pains</i></b>		
Myalgia	97	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle atrophy	1	0
Muscle discomfort	1	0
Muscle fatigue	1	0
Muscle spasms	6	0
Muscle tightness	4	0
Muscle twitching	2	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	2	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	23	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Mobility decreased	3	0
Musculoskeletal stiffness	31	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	14	0
Limb discomfort	12	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	4	0
Musculoskeletal pain	2	0
Neck pain	23	0
Pain in extremity	126	0
Rheumatic disorder	1	0
<b><i>Myopathies</i></b>		
Myopathy	1	0
Rhabdomyolysis	1	0
<b><i>Psoriatic arthropathies</i></b>		

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Earliest Reaction Date: 16-Nov-2007

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b> Muscle & tissue disorders cont'd		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	2	0
Soft tissue swelling	1	0
<i>Tendon disorders</i>		
Tendon disorder	3	0
Tendon pain	1	0
Tendonitis	3	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>514</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Skin neoplasms benign</i>		
Fibrous histiocytoma	1	0
<i>Urinary tract neoplasms unspecified malignancy NEC</i>		
Renal neoplasm	1	0
<b>Neoplasms SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Areflexia	1	0
Hyporeflexia	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	4	0
Miller Fisher syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	0
Ischaemic stroke	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	17	0
Coordination abnormal	2	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	3	0
<i>Dementia (excl Alzheimer's type)</i>		
Vascular dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	2	0
Lethargy	16	0
Loss of consciousness	9	0
Somnolence	17	0
Syncope	32	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	1	0
Fine motor skill dysfunction	1	0
Hypokinesia	3	0
Motor dysfunction	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	5	0
Facial paralysis	2	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	168	0
Sinus headache	1	0
Tension headache	3	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Mental impairment	1	0
<i>Migraine headaches</i>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> Nervous system disorders cont'd		
Migraine	15	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	2	0
<b>Multiple sclerosis acute and progressive</b>		
Multiple sclerosis	2	0
<b>Muscle tone abnormal</b>		
Hypotonia	2	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	1	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	3	0
<b>Neurologic visual problems NEC</b>		
Tunnel vision	1	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	125	0
Dizziness postural	3	0
Head discomfort	7	0
Neurological symptom	1	0
Presyncope	3	0
Unresponsive to stimuli	2	0
<b>Olfactory nerve disorders</b>		
Anosmia	1	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	8	0
Dysaesthesia	1	0
Formication	1	0
Hyperaesthesia	1	0
Hypoaesthesia	29	0
Paraesthesia	55	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	1	0
Hemiplegia	2	0
Monoplegia	2	0
Paralysis	2	0
Paraparesis	1	0
Paraplegia	1	0
<b>Peripheral neuropathies NEC</b>		
Brachial plexopathy	1	0
Neuralgic amyotrophy	1	0
Neuritis	1	0
Neuropathy peripheral	1	0
Peripheral sensory neuropathy	2	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	2	0
Seizure	8	0
Tonic clonic movements	1	0
<b>Sensory abnormalities NEC</b>		
Dysgeusia	8	0
Electric shock sensation	1	0
Neuralgia	13	0
Sensory disturbance	6	0
Sensory loss	3	0
<b>Speech and language abnormalities</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> Nervous system disorders cont'd		
Dysarthria	3	0
Speech disorder	1	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	2	0
Radiculopathy	1	0
<b>Structural brain disorders NEC</b>		
Cerebral ventricle dilatation	1	0
<b>Tremor (excl congenital)</b>		
Tremor	25	0
<b>Trigeminal disorders</b>		
Facial neuralgia	1	0
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>663</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>4</b>	<b>0</b>



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Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
<b>null SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Agitation	4	0
Anxiety	1	0
Nervousness	3	0
Stress	1	0
<i><b>Behaviour and socialisation disturbances</b></i>		
Aggression	1	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	8	0
Disorientation	6	0
<i><b>Deliria</b></i>		
Delirium	4	0
<i><b>Depressive disorders</b></i>		
Depression	3	0
<i><b>Dissociative states</b></i>		
Dissociation	1	0
Dissociative disorder	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	16	0
<i><b>Dyssomnias</b></i>		
Poor quality sleep	1	0
<i><b>Eating disorders NEC</b></i>		
Eating disorder	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Anger	3	0
Irritability	4	0
<i><b>Fluctuating mood symptoms</b></i>		
Mood swings	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	1	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	2	0
<i><b>Mental disorders NEC</b></i>		
Mental disorder	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Depressed mood	5	0
Feeling of despair	1	0
Tearfulness	4	0
<i><b>Mood disorders NEC</b></i>		
Listless	3	0
<i><b>Obsessive-compulsive disorders and symptoms</b></i>		
Obsessive-compulsive disorder	1	0
<i><b>Panic attacks and disorders</b></i>		
Panic attack	1	0
Panic reaction	1	0
<i><b>Parasomnias</b></i>		
Abnormal dreams	3	0
Sleep talking	1	0
Somnambulism	1	0
<i><b>Perception disturbances NEC</b></i>		
Near death experience	1	0
<i><b>Psychotic disorder NEC</b></i>		
Psychotic disorder	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
<i><b>Sleep disorders NEC</b></i>		
Sleep disorder	3	0
<i><b>Speech and language usage disturbances</b></i>		
Disorganised speech	1	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Suicidal ideation	1	0
<i><b>Thinking disturbances</b></i>		
Bradyphrenia	1	0
Thinking abnormal	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>93</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Incontinence	2	0
Pollakiuria	1	0
<i>Bladder disorders NEC</i>		
Urinary bladder haemorrhage	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Renal failure and impairment</i>		
Renal impairment	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
<i>Urinary tract lithiasis (excl renal)</i>		
Ureterolithiasis	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Urinary tract pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
Semen discolouration	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal pain	1	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	37	0
Hyperventilation	1	0
Hypopnoea	1	0
Respiratory arrest	2	0
Respiratory distress	1	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial disorder	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	3	0
Bronchospasm	3	0
Wheezing	8	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	48	0
Haemoptysis	1	0
Productive cough	5	0
Sputum discoloured	1	0
Sputum retention	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonia aspiration	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	6	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	8	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinonasal obstruction	1	0
Sinus congestion	1	0
Sinus disorder	2	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Pulmonary fibrosis	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal erythema	1	0
Pharyngeal swelling	5	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	2	0
<i><b>Respiratory tract disorders NEC</b></i>		
Lung disorder	1	0
<i><b>Thoracic musculoskeletal disorders</b></i>		
Respiratory muscle weakness	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	2	0
Catarrh	5	0
Choking sensation	1	0
Dry throat	3	0
Dysphonia	3	0
Oropharyngeal pain	45	0
Rhinorrhoea	20	0
Sinus pain	1	0
Sneezing	9	0
Snoring	1	0
Throat irritation	3	0
Throat tightness	3	0
Upper-airway cough syndrome	2	0

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Respiratory disorders</b> Respiratory disorders cont'd		
<b>Respiratory disorders SOC TOTAL</b>	<b>241</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	1	0
<b><i>Alopecias</i></b>		
Alopecia	1	0
<b><i>Angioedemas</i></b>		
Angioedema	2	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	9	0
Hyperhidrosis	65	0
Night sweats	5	0
<b><i>Bullous conditions</i></b>		
Blister	5	0
Erythema multiforme	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	6	0
Pain of skin	1	0
Papule	2	0
Skin burning sensation	2	0
Skin discolouration	4	0
Skin fissures	1	0
Skin lesion	1	0
Skin reaction	5	0
Skin texture abnormal	1	0
Skin tightness	2	0
Skin warm	20	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	1	0
Dermatitis allergic	9	0
Eczema	1	0
Skin irritation	3	0
Stasis dermatitis	1	0
<b><i>Erythemas</i></b>		
Erythema	75	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	3	0
<b><i>Panniculitides</i></b>		
Panniculitis	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	2	0
Pityriasis rosea	2	0
<b><i>Pruritus NEC</i></b>		
Pruritus	64	0
<b><i>Purpura and related conditions</i></b>		
Henoch-Schonlein purpura	1	0
<b><i>Pustular conditions</i></b>		
Acute generalised exanthematous pustulosis	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	44	0
Rash erythematous	10	0
Rash macular	7	0
Rash maculo-papular	3	0
Rash papular	7	0
Rash pruritic	8	0



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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash vesicular	2	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	2	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	1	0
<i>Urticarias</i>		
Idiopathic urticaria	1	0
Urticaria	32	0
Urticaria papular	1	0
<b>Skin disorders SOC TOTAL</b>	<b>416</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Hearing disability	1	0
Housebound	1	0
Loss of personal independence in daily activities	3	0
<i>Employment issues</i>		
Stress at work	1	0
<b>Social circumstances SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Blood and blood product treatment</i>		
Plasmapheresis	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Haemorrhages NEC</b></i>		
Haematoma	1	0
Haemorrhage	3	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Vein rupture	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	1	0
Flushing	10	0
Hot flush	7	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	5	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	11	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	13	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	5	0
<i><b>Vasculitides NEC</b></i>		
Cryoglobulinaemia	1	0
Vasculitis	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>60</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>4570</b>	<b>4</b>
<b>TOTAL REPORTS</b>	<b>1376</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>4</b>