

## Case Series Drug Analysis Print

**Name: FOI 21/877 Inactivated Influenza Vaccine DAP 2020**

Report Run Date: 09-Aug-2021

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

Earliest Reaction Date: 01-Jun-1998

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 2020: Virus Vaccine in 2020

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	4	0
Lymphadenopathy	34	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Pancytopenia	1	0
Pure white cell aplasia	2	0
<i><b>Neutropenias</b></i>		
Neutropenia	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	18	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	1	0
Myocardial ischaemia	1	0
<i>Mitral valvular disorders</i>		
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiac septal hypertrophy	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	4	0
Extrasystoles	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	5	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	0
Ventricular fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Endocrine disorders congenital NEC</i>		
Cystic fibrosis related diabetes	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear haemorrhage	1	0
Ear pain	9	0
Ear swelling	1	0
Otorrhoea	1	0
<i>Hearing losses</i>		
Hypoacusis	3	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	4	0
Vertigo	9	0
<b>Ear disorders SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous floaters	1	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	1	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Uveitis	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Eyelid irritation	1	0
Eyelid oedema	1	0
Swelling of eyelid	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	6	0
Eye swelling	8	0
Eyelid pain	1	0
Ocular discomfort	1	0
Periorbital swelling	2	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye inflammation	2	0
Eye irritation	3	0
Eye pruritus	3	0
Ocular hyperaemia	1	0
<i><b>Ocular sensation disorders</b></i>		
Abnormal sensation in eye	1	0
Asthenopia	1	0
Photophobia	2	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Macular detachment	1	0
Macular hole	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	1	0
Photopsia	2	0
Vision blurred	7	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	3	0
Blindness transient	2	0
Visual impairment	9	0
<b>Eye disorders SOC TOTAL</b>	<b>65</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Colitis (excl infective)</i>		
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Teeth brittle	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	65	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	6	0
Faeces hard	1	0
Faeces soft	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	8	0
Abdominal pain lower	1	0
Abdominal pain upper	22	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	12	0
Anal incontinence	1	0
Dysphagia	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	127	0
Retching	2	0
Vomiting	57	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	2	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	6	0
<i>Oral soft tissue signs and symptoms</i>		



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<b>Gastrointestinal disorders</b> Gastrointestinal disorders cont'd		
Hypoaesthesia oral	5	0
Oral pain	2	0
Oral pruritus	2	0
Paraesthesia oral	10	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	12	0
Mouth swelling	6	0
Palatal swelling	1	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	4	0
<b><i>Tongue disorders</i></b>		
Tongue ulceration	1	0
<b><i>Tongue signs and symptoms</i></b>		
Swollen tongue	6	0
Tongue discolouration	1	0
Tongue pruritus	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>385</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site joint movement impairment	2	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site pain	1	0
Application site pruritus	1	0
Application site rash	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	33	0
Chronic fatigue syndrome	2	0
Fatigue	178	0
Malaise	95	0
Sluggishness	1	0
<i>Febrile disorders</i>		
Pyrexia	115	0
<i>Feelings and sensations NEC</i>		
Chills	92	0
Feeling abnormal	19	0
Feeling cold	19	0
Feeling hot	47	0
Feeling of body temperature change	9	0
Sensation of foreign body	2	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	7	0
Illness	5	0
Induration	1	0
Influenza like illness	38	0
Local reaction	1	0
Peripheral swelling	40	0
Swelling	43	0
Swelling face	16	0
<i>Inflammations</i>		
Inflammation	7	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	5	0
Injection site bruising	2	0
Injection site discomfort	1	0
Injection site erythema	16	0
Injection site extravasation	1	0
Injection site hypersensitivity	1	0
Injection site hypertrophy	1	0
Injection site induration	3	0
Injection site inflammation	2	0
Injection site irritation	1	0
Injection site mass	3	0
Injection site movement impairment	1	0
Injection site pain	23	0

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<b>General disorders</b> General disorders cont'd		
Injection site pruritus	19	0
Injection site rash	1	0
Injection site swelling	10	0
Injection site urticaria	2	0
Injection site warmth	3	0
<b>Interactions</b>		
Drug interaction	2	0
<b>Mass conditions NEC</b>		
Mass	1	0
<b>Pain and discomfort NEC</b>		
Axillary pain	16	0
Chest discomfort	18	0
Chest pain	9	0
Discomfort	5	0
Facial pain	2	0
Pain	69	0
Tenderness	9	0
<b>Therapeutic and nontherapeutic responses</b>		
Immediate post-injection reaction	1	0
Vaccination failure	2	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	3	0
Shoulder injury related to vaccine administration	7	0
Vaccination site bruising	10	0
Vaccination site cyst	1	0
Vaccination site discolouration	2	0
Vaccination site discomfort	5	0
Vaccination site erythema	69	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	2	0
Vaccination site hypoaesthesia	2	0
Vaccination site induration	14	0
Vaccination site inflammation	11	0
Vaccination site irritation	2	0
Vaccination site joint effusion	1	0
Vaccination site joint movement impairment	5	0
Vaccination site joint pain	4	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	19	0
Vaccination site movement impairment	18	0
Vaccination site pain	119	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	27	0
Vaccination site rash	16	0
Vaccination site reaction	2	0
Vaccination site swelling	85	0
Vaccination site warmth	51	0
<b>General disorders SOC TOTAL</b>	<b>1490</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	28	0
Multiple allergies	1	0
Serum sickness-like reaction	1	0
Type III immune complex mediated reaction	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	3	0
Drug hypersensitivity	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	24	0
Anaphylactic shock	2	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorder	2	0
Immune-mediated adverse reaction	3	0
<b>Immune system disorders SOC TOTAL</b>	<b>67</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Atypical mycobacterial infections</i></b>		
Mycobacterial infection	1	0
<b><i>Bacterial infections NEC</i></b>		
Arthritis bacterial	2	0
Cellulitis	13	0
Upper respiratory tract infection bacterial	1	0
Vaccination site cellulitis	3	0
<b><i>Bone and joint infections</i></b>		
Vaccination site joint infection	1	0
<b><i>Campylobacter infections</i></b>		
Campylobacter gastroenteritis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Meningitis	1	0
<b><i>Coronavirus infections</i></b>		
COVID-19	3	0
Coronavirus infection	1	0
Suspected COVID-19	1	0
<b><i>Ear infections</i></b>		
Ear infection	1	0
Labyrinthitis	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	1	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	6	0
<b><i>Infections NEC</i></b>		
Injection site infection	1	0
Lymph gland infection	1	0
Vaccination site infection	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	27	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	2	0
Infective pulmonary exacerbation of cystic fibrosis	7	0
Lower respiratory tract infection	5	0
Pneumonia	1	0
<b><i>Molluscum contagiosum viral infections</i></b>		
Molluscum contagiosum	1	0
<b><i>Muscle and soft tissue infections</i></b>		
Soft tissue infection	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	1	0
<b><i>Staphylococcal infections</i></b>		
Staphylococcal infection	1	0
<b><i>Tuberculous infections</i></b>		
Erythema induratum	1	0
<b><i>Upper respiratory tract infections</i></b>		
Acute sinusitis	1	0
Nasopharyngitis	8	0
Rhinitis	1	0
Sinusitis	2	0
Tonsillitis	1	0
<b><i>Urinary tract infections</i></b>		
Urinary tract infection	2	0

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Post viral fatigue syndrome	2	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>107</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Foetal exposure during pregnancy	1	0
Maternal exposure during pregnancy	6	0
<i><b>Eye injuries NEC</b></i>		
Eye contusion	1	0
<i><b>Gastrointestinal and hepatobiliary procedural complications</b></i>		
Procedural vomiting	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	1	0
Product use issue	1	0
Wrong technique in product usage process	3	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Ligament sprain	1	0
Tendon rupture	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	4	0
Nerve root injury thoracic	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	2	0
<i><b>Non-site specific procedural complications</b></i>		
Administration related reaction	1	0
Injection related reaction	1	0
<i><b>Product administration errors and issues</b></i>		
Contraindicated product administered	2	0
Extra dose administered	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	1	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	4	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	9	0
Product administered to patient of inappropriate age	1	0
Product administration error	2	0
Wrong product administered	1	0
<i><b>Product monitoring errors and issues</b></i>		
Documented hypersensitivity to administered product	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	6	0
Skin abrasion	1	0
<i><b>Vaccination related complications</b></i>		
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>58</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Autoimmunity analyses</b></i>		
Antineutrophil cytoplasmic antibody positive	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	1	0
Blood glucose increased	3	0
<i><b>Faecal analyses NEC</b></i>		
White blood cells stool	1	0
<i><b>Haematological analyses NEC</b></i>		
Red blood cell sedimentation rate increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	1	0
Heart rate increased	13	0
Heart rate irregular	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature abnormal	1	0
Body temperature increased	4	0
Grip strength decreased	1	0
Weight decreased	1	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
Protein total increased	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	5	0
Blood pressure increased	5	0
<i><b>Vitamin analyses</b></i>		
Vitamin D increased	1	0
<b>Investigations SOC TOTAL</b>	<b>44</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	38	0
Food refusal	2	0
Increased appetite	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	5	0
Feeding disorder	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Pseudohypoglycaemia	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>48</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	3	0
Arthropathy	2	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	1	0
Pain in jaw	3	0
Spinal pain	1	0
<i><b>Bursal disorders</b></i>		
Bursitis	6	0
<i><b>Connective tissue disorders NEC</b></i>		
Myofascitis	1	0
Polymyalgia rheumatica	4	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	1	0
<i><b>Joint related disorders NEC</b></i>		
Periarthritis	4	0
Rotator cuff syndrome	3	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	108	0
Joint effusion	1	0
Joint range of motion decreased	1	0
Joint stiffness	5	0
Joint swelling	11	0
Joint warmth	1	0
<i><b>Muscle infections and inflammations</b></i>		
Focal myositis	1	0
Myositis	3	0
<i><b>Muscle pains</b></i>		
Myalgia	111	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle atrophy	1	0
Muscle discomfort	2	0
Muscle fatigue	6	0
Muscle spasms	10	0
Muscle swelling	1	0
Muscle tightness	3	0
Muscle twitching	2	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	13	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Extremity contracture	1	0
Limb mass	2	0
Mobility decreased	3	0
Musculoskeletal stiffness	30	0
Winged scapula	2	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	23	0
Limb discomfort	13	0
Musculoskeletal chest pain	4	0
Musculoskeletal discomfort	4	0
Neck pain	26	0
Pain in extremity	139	0
<i><b>Myopathies</b></i>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b> Muscle & tissue disorders cont'd		
Myopathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
<i>Soft tissue disorders NEC</i>		
Groin pain	2	0
Neck mass	1	0
<i>Tendon disorders</i>		
Tendonitis	4	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>566</b>	<b>0</b>

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Report Run Date: 09-Aug-2021

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Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
<i>Skin neoplasms benign</i>		
Seborrhoeic keratosis	1	0
Skin papilloma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	11	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	0
Subarachnoid haemorrhage	1	1
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	8	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	27	0
Loss of consciousness	11	0
Somnolence	19	0
Syncope	33	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	2	0
Hypokinesia	5	0
Motor dysfunction	1	0
Movement disorder	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	2	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Headache	202	0
Sinus headache	1	0
Tension headache	4	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	2	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	4	0
<i>Migraine headaches</i>		
Migraine	8	0
Migraine with aura	2	0
<i>Mononeuropathies</i>		
Nerve compression	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	2	0
<i>Narcolepsy and hypersomnia</i>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> Nervous system disorders cont'd		
Hypersomnia	4	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	1	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	110	0
Dizziness postural	3	0
Head discomfort	3	0
Presyncope	7	0
Unresponsive to stimuli	5	0
<b>Olfactory nerve disorders</b>		
Anosmia	1	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	2	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	17	0
Formication	1	0
Hyperaesthesia	1	0
Hypoaesthesia	29	0
Paraesthesia	47	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	1	0
Monoplegia	2	0
Paralysis	1	0
<b>Peripheral neuropathies NEC</b>		
Neuralgic amyotrophy	2	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	1	0
Seizure	11	0
<b>Sensory abnormalities NEC</b>		
Ageusia	3	0
Dysgeusia	6	0
Hypogeusia	1	0
Neuralgia	8	0
Restless legs syndrome	1	0
Sensory disturbance	4	0
Sensory loss	4	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	3	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	1	0
<b>Tremor (excl congenital)</b>		
Tremor	19	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>666</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	1	0
Anxiety	5	0
Stress	1	0
Tension	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Soliloquy	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	4	0
Disorientation	7	0
<b><i>Deliria</i></b>		
Delirium	1	0
<b><i>Delusional symptoms</i></b>		
Delusion	2	0
<b><i>Depressive disorders</i></b>		
Depression	2	0
<b><i>Dissociative states</i></b>		
Dissociation	2	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	12	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	2	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional disorder	1	0
Emotional distress	1	0
Euphoric mood	2	0
Irritability	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	5	0
Hallucination, auditory	1	0
Hallucination, visual	2	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	1	0
<b><i>Mood disorders NEC</i></b>		
Apathy	1	0
Listless	2	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	2	0
Panic disorder	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	1	0
Rapid eye movements sleep abnormal	1	0
<b><i>Psychotic disorder NEC</i></b>		



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
Psychotic disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	5	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
<i>Thinking disturbances</i>		
Intrusive thoughts	1	0
<i>Tic disorders</i>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>77</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Dysuria	1	0
Pollakiuria	1	0
Urinary incontinence	2	0
Urinary retention	1	0
<i><b>Bladder disorders NEC</b></i>		
Urinary bladder haemorrhage	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	2	0
Renal failure	1	0
Renal impairment	1	0
<i><b>Renal lithiasis</b></i>		
Nephrolithiasis	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	1	0
Haematuria	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Renal pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>14</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>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	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>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal disorders NEC</i>		
Vulval ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal burning sensation	1	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	1	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	30	0
Hyperventilation	2	0
Hypopnoea	2	0
Respiration abnormal	2	0
Respiratory arrest	1	0
Respiratory distress	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	1	0
Wheezing	4	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	29	0
Haemoptysis	2	0
Productive cough	2	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Pulmonary pain	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	2	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	1	0
Nasal polyps	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	4	0
Pharyngeal ulceration	1	0
Tonsillar hypertrophy	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	4	2
<i><b>Respiratory signs and symptoms NEC</b></i>		
Painful respiration	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Lung disorder	1	0
Respiratory disorder	1	0
Respiratory tract inflammation	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	1	0
Dry throat	1	0
Dysphonia	2	0
Nasal discomfort	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	31	0
Rhinorrhoea	14	0
Sinus pain	2	0
Sneezing	6	0
Throat irritation	2	0
Throat tightness	3	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>165</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Alopecias</b></i>		
Alopecia	1	0
<i><b>Angioedemas</b></i>		
Angioedema	4	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	10	0
Hyperhidrosis	30	0
Miliaria	2	0
Night sweats	6	0
<i><b>Bullous conditions</b></i>		
Blister	4	0
Blister rupture	1	0
Blood blister	2	0
Stevens-Johnson syndrome	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	3	0
Pain of skin	2	0
Papule	2	0
Scar pain	1	0
Sensitive skin	3	0
Skin discolouration	3	0
Skin disorder	1	0
Skin induration	3	0
Skin lesion	1	0
Skin reaction	7	0
Skin warm	18	0
Skin weeping	2	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis	5	0
Dermatitis allergic	7	0
Eczema	1	0
Skin irritation	3	0
<i><b>Dermatitis ascribed to specific agent</b></i>		
Drug eruption	2	0
<i><b>Erythemas</b></i>		
Erythema	78	0
<i><b>Papulosquamous conditions</b></i>		
Pityriasis rosea	1	0
<i><b>Photosensitivity and photodermatosis conditions</b></i>		
Photosensitivity reaction	2	0
<i><b>Pruritus NEC</b></i>		
Pruritus	88	0
<i><b>Psoriatic conditions</b></i>		
Psoriasis	3	0
<i><b>Purpura and related conditions</b></i>		
Henoch-Schonlein purpura	1	0
Purpura	1	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Nodular rash	1	0
Rash	45	0
Rash erythematous	14	0
Rash macular	5	0
Rash maculo-papular	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash papular	6	0
Rash pruritic	11	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin erosion	1	0
<b><i>Skin haemorrhages</i></b>		
Skin haemorrhage	1	0
<b><i>Skin vasculitides</i></b>		
Vasculitic rash	1	0
<b><i>Urticarias</i></b>		
Cold urticaria	1	0
Haemorrhagic urticaria	1	0
Urticaria	48	0
<b>Skin disorders SOC TOTAL</b>	<b>435</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	1	0
Immobile	1	0
Impaired work ability	3	0
Loss of personal independence in daily activities	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>		
Transfusion	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>2</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Aortic aneurysms and dissections</b></i>		
Aortic aneurysm	1	0
<i><b>Arterial infections and inflammations</b></i>		
Giant cell arteritis	1	0
<i><b>Blood pressure disorders NEC</b></i>		
Blood pressure fluctuation	1	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	3	0
<i><b>Haemorrhages NEC</b></i>		
Haemorrhage	2	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Deep vein thrombosis	1	1
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	1	0
Flushing	3	0
Hot flush	4	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	5	0
Vasoconstriction	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	8	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	3	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	3	0
Orthostatic hypotension	1	0
<i><b>Vasculitides NEC</b></i>		
Granulomatosis with polyangiitis	1	0
Vasculitis	3	0
<b>Vascular disorders SOC TOTAL</b>	<b>42</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>4376</b>	<b>6</b>
<b>TOTAL REPORTS</b>	<b>1340</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>6</b>