

## Case Series Drug Analysis Print

Name: FOI 21/1164 Inactivated influenza DAP

Report Run Date: 24-Nov-2021

Data Lock Date: 17-Oct-2021 22:57:05

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.0

FOI 21/1164 All spontaneous suspected UK Adverse Drug Reaction  
Inactivated influenza (ADR) reports associated with influenza virus  
DAP: (inactivated) vaccine

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Haematological disorders</b></i>		
Mast cell activation syndrome	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	8	0
Lymphadenopathy	66	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	2	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>82</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	29	0
<i><b>Coronary artery disorders NEC</b></i>		
Arteriosclerosis coronary artery	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Angina pectoris	1	0
Myocardial infarction	2	0
Myocardial ischaemia	1	0
<i><b>Mitral valvular disorders</b></i>		
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiac septal hypertrophy	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	1	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	1	0
Pleuropericarditis	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	4	0
Cardiac flutter	1	0
Extrasystoles	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	6	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	4	0
Supraventricular tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	3	0
Pulseless electrical activity	1	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>64</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>Neurological disorders congenital NEC</i>		
Early onset primary dystonia	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	2	0
<b>Congenital disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear congestion	1	0
Ear discomfort	4	0
Ear haemorrhage	1	0
Ear pain	16	0
Ear swelling	2	0
Otorrhoea	1	0
<i><b>Hearing losses</b></i>		
Deafness	1	0
Deafness neurosensory	1	0
Deafness unilateral	1	0
Hypoacusis	4	0
Sudden hearing loss	1	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	2	0
<i><b>Inner ear signs and symptoms</b></i>		
Tinnitus	14	0
Vertigo	22	0
<b>Ear disorders SOC TOTAL</b>	<b>71</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	2	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>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<b><i>Choroid and vitreous structural change, deposit and degeneration</i></b>		
Vitreous floaters	2	0
<b><i>Conjunctival infections, irritations and inflammations</i></b>		
Photoelectric conjunctivitis	1	0
<b><i>Corneal infections, oedemas and inflammations</i></b>		
Keratitis	1	0
<b><i>Eyelid movement disorders</i></b>		
Blepharospasm	2	0
<b><i>Iris and ciliary body structural change, deposit and degeneration</i></b>		
Eye colour change	1	0
<b><i>Iris and uveal tract infections, irritations and inflammations</i></b>		
Uveitis	1	0
<b><i>Lacrimation disorders</i></b>		
Lacrimation increased	1	0
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Eyelid irritation	1	0
Eyelid oedema	1	0
Swelling of eyelid	4	0
<b><i>Ocular bleeding and vascular disorders NEC</i></b>		
Eye haemorrhage	1	0
<b><i>Ocular disorders NEC</i></b>		
Eye oedema	1	0
Eye pain	8	0
Eye swelling	15	0
Eyelid pain	1	0
Ocular discomfort	1	0
Periorbital swelling	4	0
Vitreous disorder	1	0
<b><i>Ocular infections, inflammations and associated manifestations</i></b>		
Eye discharge	2	0
Eye inflammation	2	0
Eye irritation	4	0
Eye pruritus	3	0
Ocular hyperaemia	1	0
<b><i>Ocular sensation disorders</i></b>		
Abnormal sensation in eye	1	0
Asthenopia	1	0
Foreign body sensation in eyes	1	0
Photophobia	4	0
<b><i>Optic disc abnormalities NEC</i></b>		
Papilloedema	1	0
<b><i>Retinal structural change, deposit and degeneration</i></b>		
Macular detachment	1	0
Macular hole	1	0
<b><i>Visual disorders NEC</i></b>		
Diplopia	2	0
Metamorphopsia	1	0
Photopsia	5	0
Vision blurred	14	0
<b><i>Visual field disorders</i></b>		
Visual field defect	1	0
<b><i>Visual impairment and blindness (excl colour blindness)</i></b>		
Blindness	5	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Blindness transient	2	0
Blindness unilateral	1	0
Visual impairment	13	0
<b>Visual pathway disorders</b>		
Optic nerve disorder	2	0
<b>Eye disorders SOC TOTAL</b>	<b>115</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<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	3	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	124	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	7	0
Faeces hard	1	0
Faeces soft	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	9	0
Flatulence	6	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	19	0
Abdominal pain lower	2	0
Abdominal pain upper	33	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	5	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	3	0
Change of bowel habit	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal tract irritation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	23	0
Anal incontinence	2	0
Dysphagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
Irritable bowel syndrome	2	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	2	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	214	0
Retching	3	0
Vomiting	101	0
Vomiting projectile	1	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Haematemesis	1	1
Haematochezia	2	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	6	0
Salivary hypersecretion	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	7	0
Lip erythema	1	0
Lip pain	1	0
Oral discomfort	1	0
Oral pain	4	0
Oral pruritus	2	0
Paraesthesia oral	10	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	19	0
Mouth swelling	7	0
Palatal swelling	1	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	5	0
<b><i>Tongue disorders</i></b>		
Tongue ulceration	1	0
<b><i>Tongue signs and symptoms</i></b>		
Swollen tongue	11	0
Tongue discolouration	1	0
Tongue pruritus	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>663</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site erythema	1	0
Administration site joint movement impairment	2	0
Administration site nerve damage	1	0
Administration site pain	1	0
Administration site swelling	4	0
<b><i>Application and instillation site reactions</i></b>		
Application site hypoaesthesia	1	0
Application site joint pain	1	0
Application site pain	4	0
Application site paraesthesia	1	0
Application site pruritus	1	0
Application site rash	1	0
Application site swelling	2	0
<b><i>Asthenic conditions</i></b>		
Asthenia	53	0
Chronic fatigue syndrome	3	0
Fatigue	275	0
Malaise	138	0
Sluggishness	1	0
<b><i>Body temperature altered</i></b>		
Hypothermia	1	0
<b><i>Febrile disorders</i></b>		
Pyrexia	175	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	140	0
Feeling abnormal	37	0
Feeling cold	32	0
Feeling hot	66	0
Feeling of body temperature change	13	0
Sensation of foreign body	2	0
Thirst	3	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	7	0
Gait inability	3	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	12	0
Illness	20	0
Induration	2	0
Influenza like illness	66	0
Local reaction	1	0
Peripheral swelling	73	0
Swelling	53	0
Swelling face	25	0
<b><i>Inflammations</i></b>		
Inflammation	12	0
Systemic inflammatory response syndrome	1	0
<b><i>Injection site reactions</i></b>		
Injected limb mobility decreased	10	0
Injection site bruising	2	0
Injection site discomfort	3	0
Injection site erythema	23	0
Injection site extravasation	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site hypersensitivity	2	0
Injection site hypertrophy	1	0
Injection site induration	3	0
Injection site inflammation	9	0
Injection site irritation	1	0
Injection site mass	5	0
Injection site movement impairment	2	0
Injection site pain	32	0
Injection site paraesthesia	1	0
Injection site pruritus	24	0
Injection site rash	1	0
Injection site reaction	3	0
Injection site swelling	14	0
Injection site urticaria	2	0
Injection site warmth	3	0
<b>Interactions</b>		
Drug interaction	3	0
<b>Mass conditions NEC</b>		
Mass	1	0
<b>Pain and discomfort NEC</b>		
Axillary pain	23	0
Chest discomfort	35	0
Chest pain	23	0
Discomfort	5	0
Facial pain	6	0
Pain	110	0
Tenderness	11	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	197	1
Adverse event	1	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Therapeutic product effect decreased	1	0
Vaccination failure	2	0
<b>Ulcers NEC</b>		
Ulcer	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	5	0
Shoulder injury related to vaccine administration	14	0
Vaccination site bruising	14	0
Vaccination site cyst	1	0
Vaccination site discharge	1	0
Vaccination site discolouration	3	0
Vaccination site discomfort	8	0
Vaccination site erythema	99	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	5	0
Vaccination site hypoaesthesia	2	0
Vaccination site induration	21	0
Vaccination site inflammation	14	0
Vaccination site injury	1	0
Vaccination site irritation	2	0
Vaccination site joint effusion	1	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	8	0
Vaccination site joint pain	6	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	24	0
Vaccination site movement impairment	23	0
Vaccination site nerve damage	1	0
Vaccination site pain	161	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	36	0
Vaccination site rash	19	0
Vaccination site reaction	5	0
Vaccination site swelling	113	0
Vaccination site urticaria	1	0
Vaccination site vesicles	1	0
Vaccination site warmth	65	0
<b>General disorders SOC TOTAL</b>	<b>2456</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatic steatosis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</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	46	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 chemicals	1	0
Allergy to vaccine	8	0
Drug hypersensitivity	5	0
Food allergy	2	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	38	0
Anaphylactic shock	5	0
Anaphylactoid reaction	2	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	2	0
Immune system disorder	3	0
Immune-mediated adverse reaction	3	0
<b>Immune system disorders SOC TOTAL</b>	<b>118</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Atypical mycobacterial infections</b></i>		
Mycobacterial infection	1	0
<i><b>Bacterial infections NEC</b></i>		
Administration site cellulitis	2	0
Arthritis bacterial	2	0
Bacterial infection	2	0
Cellulitis	15	0
Upper respiratory tract infection bacterial	1	0
Vaccination site cellulitis	4	0
<i><b>Bone and joint infections</b></i>		
Vaccination site joint infection	1	0
<i><b>Campylobacter infections</b></i>		
Campylobacter gastroenteritis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Encephalitis	1	0
Meningitis	1	0
Myelitis	1	0
<i><b>Coronavirus infections</b></i>		
COVID-19	5	0
Coronavirus infection	1	0
Suspected COVID-19	2	0
<i><b>Ear infections</b></i>		
Ear infection	1	0
Labyrinthitis	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	1	0
<i><b>Herpes viral infections</b></i>		
Herpes zoster	6	0
Oral herpes	2	0
<i><b>Infections NEC</b></i>		
Infection	1	0
Injection site infection	1	0
Lymph gland infection	1	0
Vaccination site infection	3	0
<i><b>Influenza viral infections</b></i>		
Influenza	45	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	4	0
Infective pulmonary exacerbation of cystic fibrosis	7	0
Lower respiratory tract infection	9	0
Pneumonia	2	1
<i><b>Molluscum contagiosum viral infections</b></i>		
Molluscum contagiosum	1	0
<i><b>Muscle and soft tissue infections</b></i>		
Soft tissue infection	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	2	0
<i><b>Staphylococcal infections</b></i>		
Furuncle	1	0
Staphylococcal infection	1	0
<i><b>Tuberculous infections</b></i>		
Erythema induratum	1	0
<i><b>Upper respiratory tract infections</b></i>		



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<b>Infections</b>		
Infections cont'd		
Acute sinusitis	1	0
Laryngitis	1	0
Nasopharyngitis	18	0
Rhinitis	2	0
Sinusitis	4	0
Tonsillitis	1	0
<b>Urinary tract infections</b>		
Urinary tract infection	2	0
<b>Viral infections NEC</b>		
Gastroenteritis viral	1	0
Post viral fatigue syndrome	2	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>164</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>		
Foetal exposure during pregnancy	1	0
Maternal exposure during pregnancy	12	0
<i><b>Eye injuries NEC</b></i>		
Eye contusion	1	0
<i><b>Gastrointestinal and hepatobiliary procedural complications</b></i>		
Procedural vomiting	2	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	29	0
Product use issue	1	0
Vaccination error	1	0
Wrong technique in product usage process	4	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Ligament sprain	1	0
Muscle injury	3	0
Muscle strain	1	0
Tendon rupture	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	10	0
Nerve root injury thoracic	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	4	0
<i><b>Non-site specific procedural complications</b></i>		
Administration related reaction	1	0
Injection related reaction	1	0
<i><b>Off label uses</b></i>		
Off label use	1	0
<i><b>Overdoses NEC</b></i>		
Overdose	1	0
<i><b>Product administration errors and issues</b></i>		
Accidental underdose	1	0
Contraindicated product administered	2	0
Extra dose administered	3	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	14	0
Product administered to patient of inappropriate age	5	0
Product administration error	3	0
Wrong product administered	1	0
<i><b>Product monitoring errors and issues</b></i>		
Documented hypersensitivity to administered product	3	0
<i><b>Site specific injuries NEC</b></i>		
Limb injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	14	0
Skin abrasion	1	0
<i><b>Vaccination related complications</b></i>		
Adverse event following immunisation	1	0
Vaccination complication	4	0
<b>Injuries SOC TOTAL</b>	<b>137</b>	<b>0</b>

## Case Series Drug Analysis Print

Name: FOI 21/1164 Inactivated influenza DAP

Report Run Date: 24-Nov-2021  
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 17-Oct-2021 22:57:05  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Autoimmunity analyses</i></b>		
Antineutrophil cytoplasmic antibody positive	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Oxygen saturation decreased	3	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose decreased	1	0
Blood glucose increased	3	0
<b><i>ECG investigations</i></b>		
Electrocardiogram QT prolonged	1	0
<b><i>Faecal analyses NEC</i></b>		
White blood cells stool	1	0
<b><i>Haematological analyses NEC</i></b>		
Red blood cell sedimentation rate increased	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	1	0
Heart rate decreased	5	0
Heart rate increased	18	0
Heart rate irregular	3	0
<b><i>Investigations NEC</i></b>		
Blood test abnormal	1	0
Laboratory test abnormal	1	0
<b><i>Liver function analyses</i></b>		
Liver function test abnormal	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature abnormal	1	0
Body temperature fluctuation	1	0
Body temperature increased	11	0
Grip strength decreased	1	0
Respiratory rate increased	2	0
Weight decreased	2	0
Weight increased	2	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	1	0
Protein total increased	1	0
<b><i>Red blood cell analyses</i></b>		
Haemoglobin decreased	2	0
<b><i>Reproductive hormone analyses</i></b>		
Blood testosterone decreased	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Peak expiratory flow rate decreased	1	0
<b><i>Urinalysis NEC</i></b>		
Urine analysis abnormal	1	0
<b><i>Urinary tract function analyses NEC</i></b>		
Urine output decreased	1	0
Urine output increased	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure decreased	6	0
Blood pressure increased	7	0
<b><i>Vitamin analyses</i></b>		
Vitamin D increased	1	0
<b>Investigations SOC TOTAL</b>	<b>84</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	60	0
Food refusal	2	0
Increased appetite	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	1	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	7	0
Feeding disorder	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Pseudohypoglycaemia	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>75</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	7	0
Arthropathy	3	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	3	0
Pain in jaw	4	0
Spinal pain	1	0
<i><b>Bursal disorders</b></i>		
Bursitis	8	0
<i><b>Connective tissue disorders NEC</b></i>		
Myofascitis	1	0
Polymyalgia rheumatica	10	0
Sjogren's syndrome	1	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	1	0
<i><b>Joint related disorders NEC</b></i>		
Periarthritis	11	0
Rotator cuff syndrome	5	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	180	0
Joint effusion	1	0
Joint range of motion decreased	1	0
Joint stiffness	8	0
Joint swelling	16	0
Joint warmth	1	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Systemic lupus erythematosus	1	0
<i><b>Muscle infections and inflammations</b></i>		
Focal myositis	1	0
Myositis	3	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	1	0
Myalgia	174	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle atrophy	1	0
Muscle discomfort	2	0
Muscle fatigue	10	0
Muscle mass	1	0
Muscle spasms	18	0
Muscle swelling	2	0
Muscle tightness	3	0
Muscle twitching	6	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	24	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Extremity contracture	1	0
Limb mass	2	0
Mobility decreased	7	0
Musculoskeletal stiffness	44	0
Winged scapula	2	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	32	0
Limb discomfort	28	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Musculoskeletal chest pain	8	0
Musculoskeletal discomfort	7	0
Neck pain	36	0
Pain in extremity	235	0
<b>Myopathies</b>		
Myopathy	2	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	2	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	1	0
Groin pain	3	0
Neck mass	1	0
<b>Spondyloarthropathies</b>		
Spondylitis	1	0
<b>Tendon disorders</b>		
Tendonitis	4	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>925</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>Endocrine neoplasms malignant and unspecified NEC</b></i>		
Neuroendocrine tumour	1	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	3	0
<i><b>Neoplasms unspecified malignancy and site unspecified NEC</b></i>		
Neoplasm	1	0
<i><b>Neurofibrosarcomas</b></i>		
Neurofibrosarcoma	1	0
<i><b>Skin melanomas (excl ocular)</b></i>		
Malignant melanoma	1	0
<i><b>Skin neoplasms benign</b></i>		
Seborrhoeic keratosis	1	0
Skin papilloma	2	0
<i><b>Soft tissue neoplasms benign NEC</b></i>		
Lipoma	1	0
<i><b>Uterine neoplasms benign</b></i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>12</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>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	19	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	0
Cerebrovascular accident	3	0
Subarachnoid haemorrhage	1	1
<i>Chronic polyneuropathies</i>		
Acrodynia	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	12	0
Coordination abnormal	1	0
Dysstasia	7	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
Neuromyelitis optica spectrum disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	2	0
Lethargy	40	0
Loss of consciousness	18	0
Somnolence	24	0
Syncope	42	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	2	0
Hypokinesia	6	0
Motor dysfunction	1	0
Movement disorder	3	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	3	0
Facial paralysis	3	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	313	0
Sinus headache	3	0
Tension headache	6	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b>Hydrocephalic conditions</b>		
Hydrocephalus	1	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	2	0
<b>Memory loss (excl dementia)</b>		
Amnesia	3	0
Memory impairment	2	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	1	0
Disturbance in attention	4	0
<b>Migraine headaches</b>		
Migraine	18	0
Migraine with aura	2	0
<b>Mononeuropathies</b>		
Nerve compression	2	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	3	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	7	0
Narcolepsy	1	0
<b>Nervous system disorders NEC</b>		
Cerebral disorder	1	0
Nervous system disorder	1	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	168	0
Dizziness postural	9	0
Head discomfort	6	0
Presyncope	10	0
Slow response to stimuli	1	0
Unresponsive to stimuli	5	0
<b>Olfactory nerve disorders</b>		
Anosmia	1	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	4	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	24	0
Formication	2	0
Hyperaesthesia	1	0
Hypoaesthesia	48	0
Paraesthesia	75	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	1	0
Monoplegia	3	0
Paralysis	1	0
Paresis	1	0
<b>Peripheral neuropathies NEC</b>		
Neuralgic amyotrophy	3	0
Neuropathy peripheral	7	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	1	0
Seizure	13	0
<b>Sensory abnormalities NEC</b>		
Ageusia	3	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Dysgeusia	9	0
Hypogeusia	1	0
Neuralgia	14	0
Restless legs syndrome	1	0
Sensory disturbance	7	0
Sensory loss	5	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	2	0
Speech disorder	2	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculitis brachial	5	0
<b><i>Structural brain disorders NEC</i></b>		
Brain injury	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	34	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1046</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
<i>Unintended pregnancies</i>		
Pregnancy with contraceptive device	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>3</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	9	0
Stress	3	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Soliloquy	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	1	0
<i>Confusion and disorientation</i>		
Confusional state	8	0
Disorientation	11	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Delusional symptoms</i>		
Delusion	2	0
<i>Depressive disorders</i>		
Depression	3	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	18	0
Middle insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	3	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Emotional distress	1	0
Euphoric mood	2	0
Irritability	5	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	6	0
Hallucination, auditory	1	0
Hallucination, visual	2	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	2	0
<i>Panic attacks and disorders</i>		
Panic attack	3	0
Panic disorder	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i><b>Parasomnias</b></i>		
Abnormal dreams	4	0
Rapid eye movements sleep abnormal	1	0
<i><b>Psychotic disorder NEC</b></i>		
Psychotic disorder	1	0
<i><b>Sleep disorders NEC</b></i>		
Sleep disorder	12	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Completed suicide	1	1
Suicidal ideation	1	0
<i><b>Thinking disturbances</b></i>		
Intrusive thoughts	1	0
<i><b>Tic disorders</b></i>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>120</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>		
Bladder discomfort	1	0
Dysuria	3	0
Pollakiuria	3	0
Urinary incontinence	2	0
Urinary retention	2	0
<i><b>Bladder disorders NEC</b></i>		
Urinary bladder haemorrhage	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	3	0
Renal failure	1	0
Renal impairment	1	0
Renal injury	1	0
<i><b>Renal lithiasis</b></i>		
Nephrolithiasis	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	1	0
Haematuria	2	0
Urine abnormality	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Polyuria	1	0
Renal pain	3	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>27</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast disorders NEC</b></i>		
Gynaecomastia	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast pain	1	0
Breast swelling	2	0
Breast tenderness	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	1	0
Intermenstrual bleeding	2	0
Menstruation irregular	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	3	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	2	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital discomfort	1	0
Pelvic pain	1	0
<i><b>Vaginal and vulval infections and inflammations</b></i>		
Vulvovaginal inflammation	2	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vulval ulceration	2	0
<i><b>Vulvovaginal signs and symptoms</b></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>25</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	55	0
Hyperventilation	3	0
Hypopnoea	4	0
Respiration abnormal	2	0
Respiratory arrest	1	0
Respiratory distress	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	5	0
Wheezing	9	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	1	0
Cough	49	0
Haemoptysis	2	0
Productive cough	6	0
Sputum discoloured	1	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	6	0
Nasal inflammation	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	2	0
Nasal polyps	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
Sinus disorder	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	5	0
Pharyngeal ulceration	1	0
Tonsillar hypertrophy	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary congestion	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	2	1
<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 congestion	1	0
Respiratory tract inflammation	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	3	0
Dry throat	1	0
Dysphonia	5	0
Laryngeal pain	1	0
Nasal discomfort	1	0
Oropharyngeal discomfort	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Oropharyngeal pain	55	0
Rhinorrhoea	19	0
Sinus pain	2	0
Sneezing	14	0
Throat irritation	4	0
Throat tightness	4	0
Upper respiratory tract congestion	2	0
Upper-airway cough syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>287</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Acnes</i>		
Acne	3	0
<i>Alopecias</i>		
Alopecia	1	0
<i>Angioedemas</i>		
Angioedema	8	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	15	0
Hyperhidrosis	52	0
Miliaria	3	0
Night sweats	6	0
<i>Bullous conditions</i>		
Blister	4	0
Blister rupture	1	0
Blood blister	2	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Pain of skin	2	0
Papule	3	0
Scar pain	1	0
Sensitive skin	3	0
Skin burning sensation	2	0
Skin discolouration	5	0
Skin disorder	2	0
Skin induration	3	0
Skin lesion	1	0
Skin reaction	12	0
Skin swelling	1	0
Skin warm	25	0
Skin weeping	3	0
<i>Dermatitis and eczema</i>		
Dermatitis	8	0
Dermatitis allergic	20	0
Eczema	4	0
Skin irritation	4	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
<i>Erythemas</i>		
Erythema	102	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Pityriasis rosea	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	2	0
<i>Pilar disorders NEC</i>		
Piloerection	1	0
<i>Pruritus NEC</i>		

## Case Series Drug Analysis Print

**Name: FOI 21/1164 Inactivated influenza DAP**

Report Run Date: 24-Nov-2021  
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 17-Oct-2021 22:57:05  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Pruritus	124	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	5	0
<b><i>Purpura and related conditions</i></b>		
Henoch-Schonlein purpura	1	0
Petechiae	1	0
Purpura	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Nodular rash	1	0
Rash	68	0
Rash erythematous	18	0
Rash macular	7	0
Rash maculo-papular	1	0
Rash papular	7	0
Rash pruritic	14	0
Rash vesicular	2	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	2	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>		
Hypersensitivity vasculitis	1	0
Vasculitic rash	1	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	1	0
<b><i>Urticarias</i></b>		
Cold urticaria	1	0
Haemorrhagic urticaria	1	0
Urticaria	74	0
Urticaria chronic	1	0
<b>Skin disorders SOC TOTAL</b>	<b>644</b>	<b>0</b>

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	2	0
Immobile	3	0
Impaired work ability	4	0
Loss of personal independence in daily activities	6	0
<i>Social issues NEC</i>		
Impaired quality of life	1	0
<b>Social circumstances SOC TOTAL</b>	<b>16</b>	<b>0</b>

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Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.0

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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**Name: FOI 21/1164 Inactivated influenza DAP**

Report Run Date: 24-Nov-2021  
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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	4	0
<i>Haemorrhages NEC</i>		
Haematoma	2	0
Haemorrhage	2	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	2	1
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	6	0
Hot flush	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	12	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	10	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	5	0
<i>Vascular hypotensive disorders</i>		
Hypotension	9	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Granulomatosis with polyangiitis	1	0
Vasculitis	3	0
<b>Vascular disorders SOC TOTAL</b>	<b>69</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>7219</b>	<b>10</b>
<b>TOTAL REPORTS</b>	<b>2381</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>10</b>