

## Case Series Drug Analysis Print

### Name: FOI 21/242 - Inactivated influenza vaccine Drug Analysis Print

Report Run Date: 07-Apr-2021  
Data Lock Date: 31-Mar-2021 18:30:04  
Earliest Reaction Date: 01-Jul-2004  
MedDRA Version: MedDRA 23.1

FOI 21/242 - Inactivated influenza vaccine Drug Analysis Print.  
Inactivated influenza vaccine Drug Analysis Print: Contains all cases relating to the inactivated influenza vaccine between 01/01/2019 and 31/12/2019.

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

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

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i>		
Branchial cyst	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear discomfort	2	0
Ear pain	5	0
Ear pruritus	1	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness unilateral	1	0
Hypoacusis	3	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Meniere's disease	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	10	0
<b>Ear disorders SOC TOTAL</b>	<b>34</b>	<b>0</b>

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

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



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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Lip swelling	6	0
Mouth swelling	4	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	1	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	1	0
Mouth ulceration	4	0
Stomatitis	1	0
<b><i>Tongue disorders</i></b>		
Glossitis	1	0
Tongue ulceration	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	3	0
Swollen tongue	8	0
Tongue discolouration	1	0
Tongue eruption	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>372</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site vesicles	1	0
Injection site warmth	6	0
<b>Interactions</b>		
Drug interaction	3	0
<b>Mass conditions NEC</b>		
Mass	2	0
<b>Necrosis NEC</b>		
Necrosis	1	0
<b>Oedema NEC</b>		
Oedema	1	0
<b>Pain and discomfort NEC</b>		
Axillary pain	6	0
Chest discomfort	12	0
Chest pain	10	0
Discomfort	5	0
Facial pain	1	0
Pain	88	0
Tenderness	5	0
<b>Therapeutic and nontherapeutic responses</b>		
Drug ineffective	1	0
Therapeutic response unexpected	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	2	0
Vaccination site bruising	8	0
Vaccination site coldness	1	0
Vaccination site discharge	1	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site erythema	68	0
Vaccination site hypersensitivity	1	0
Vaccination site induration	9	0
Vaccination site inflammation	14	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	1	0
Vaccination site mass	22	0
Vaccination site movement impairment	9	0
Vaccination site pain	82	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	18	0
Vaccination site rash	11	0
Vaccination site reaction	6	0
Vaccination site scab	1	0
Vaccination site swelling	75	0
Vaccination site urticaria	1	0
Vaccination site vesicles	4	0
Vaccination site warmth	34	0
<b>General disorders SOC TOTAL</b>	<b>1274</b>	<b>6</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	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>Allergic conditions NEC</i>		
Hypersensitivity	17	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
Food allergy	1	0
Reaction to excipient	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	16	0
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	2	0
<i>Vasculitides</i>		
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>54</b>	<b>1</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>		
Cellulitis	11	0
Vaccination site cellulitis	2	0
<b><i>Bone and joint infections</i></b>		
Intervertebral discitis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	1	0
<b><i>Ear infections</i></b>		
Labyrinthitis	2	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	1	0
Eye infection	1	0
Hordeolum	1	0
<b><i>Fungal infections NEC</i></b>		
Ear infection fungal	1	0
<b><i>Hepatobiliary and spleen infections</i></b>		
Liver abscess	1	0
<b><i>Herpes viral infections</i></b>		
Genital herpes	1	0
Herpes simplex reactivation	1	0
Herpes zoster	7	0
Oral herpes	4	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	2	0
Injection site abscess	1	0
Localised infection	2	0
<b><i>Infectious transmissions</i></b>		
Infection via vaccinee	2	0
Vaccine virus shedding	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	35	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	1	0
Lower respiratory tract infection	10	0
Pneumonia	5	1
<b><i>Pseudomonal infections</i></b>		
Pseudomonas infection	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	2	0
Septic shock	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Pustule	1	0
Vaccination site pustule	1	0
<b><i>Streptococcal infections</i></b>		
Pneumonia pneumococcal	1	0
<b><i>Upper respiratory tract infections</i></b>		
Laryngitis	1	0
Nasopharyngitis	14	0
Pharyngitis	2	0

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

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Cerebral injuries NEC</b></i>		
Brain herniation	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure during pregnancy	7	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Muscle injury	1	0
Muscle strain	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	2	0
<i><b>Product administration errors and issues</b></i>		
Contraindicated product administered	1	0
Extra dose administered	2	0
Inappropriate schedule of product administration	1	0
Product administered at inappropriate site	5	0
Product administered to patient of inappropriate age	2	0
Product dose omission issue	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	6	0
<i><b>Vaccination related complications</b></i>		
Vaccination complication	1	0
Vaccination failure	5	0
<b>Injuries SOC TOTAL</b>	<b>39</b>	<b>0</b>



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

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

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

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

## Case Series Drug Analysis Print

### Name: FOI 21/242 - Inactivated influenza vaccine Drug Analysis Print

Report Run Date: 07-Apr-2021  
 Earliest Reaction Date: 01-Jul-2004

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Pain in extremity	91	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	3	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	4	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	1	0
Groin pain	1	0
Neck mass	2	0
<b><i>Spondyloarthropathies</i></b>		
Arthritis reactive	1	0
<b><i>Tendon disorders</i></b>		
Tendon pain	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>486</b>	<b>0</b>

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MedDRA Version: MedDRA 23.1

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

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Areflexia	3	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	16	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebellar stroke	1	0
Cerebral haemorrhage	1	0
Cerebral infarction	1	0
Cerebrovascular accident	2	1
Ischaemic stroke	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	10	0
Coordination abnormal	2	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	32	0
Loss of consciousness	13	0
Somnolence	14	0
Syncope	26	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	3	0
Hypokinesia	1	0
Movement disorder	3	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	5	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Headache	151	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	2	0
<i>Migraine headaches</i>		

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



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Vocal cord paralysis	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>553</b>	<b>1</b>

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

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

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder spasm	1	0
Pollakiuria	1	0
Urinary retention	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
IgA nephropathy	1	0
Nephrotic syndrome	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	5	0
Chronic kidney disease	1	0
Renal impairment	1	0
<i><b>Renal vascular and ischaemic conditions</b></i>		
Renal tubular injury	1	0
<i><b>Urethral infections and inflammations</b></i>		
Urethritis noninfective	1	0
<i><b>Urinary abnormalities</b></i>		
Haematuria	4	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Renal pain	3	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>21</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>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal disorder	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	2	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
Respiratory disorders cont'd		
Throat irritation	2	0
Throat tightness	10	0
Upper-airway cough syndrome	3	0
<b>Respiratory disorders SOC TOTAL</b>	<b>247</b>	<b>1</b>



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

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash maculo-papular	5	0
Rash papular	4	0
Rash pruritic	6	0
Rash vesicular	2	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	1	0
Subcutaneous emphysema	1	0
<b><i>Skin vasculitides</i></b>		
Hypersensitivity vasculitis	1	0
Palpable purpura	2	0
Vasculitic rash	3	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	1	0
<b><i>Urticarias</i></b>		
Urticaria	28	0
<b>Skin disorders SOC TOTAL</b>	<b>365</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	1	0
Impaired work ability	1	0
Loss of personal independence in daily activities	3	0
<b>Social circumstances SOC TOTAL</b>	<b>5</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	2	0
<i><b>Arterial infections and inflammations</b></i>		
Giant cell arteritis	1	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	4	0
Shock	2	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Vein disorder	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Flushing	7	0
Hot flush	5	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Ischaemic limb pain	1	0
Peripheral coldness	2	0
Poor peripheral circulation	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	9	0
<i><b>Varicose veins NEC</b></i>		
Varicose vein	2	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	6	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	6	0
Orthostatic hypotension	1	0
<i><b>Vasculitides NEC</b></i>		
Vasculitis	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>52</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>3948</b>	<b>11</b>
<b>TOTAL REPORTS</b>	<b>1145</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>11</b>