

Case Series Drug Analysis Print

Name: FOI 19-459 Inactivated Influenza DAP

Report Run Date: 08-Oct-2019
Data Lock Date: 07-Oct-2019 19:00:04
Earliest Reaction Date: 09-Oct-1963
MedDRA Version: MedDRA 22.0

FOI 19-459 Inactivated Inactivated influenza vaccine Drug Analysis Print. All
Influenza DAP: UK spontaneous suspected inactivated influenza
vaccine cases received up to and including the 7th
October 2019.

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Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	10	0
Anaemias haemolytic NEC		
Haemolytic anaemia	6	1
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	6	0
Anaemias haemolytic mechanical factor		
Microangiopathic haemolytic anaemia	2	0
Bleeding tendencies		
Increased tendency to bruise	2	0
Spontaneous haemorrhage	1	0
Coagulation factor deficiencies		
Acquired haemophilia	1	0
Acquired haemophilia with anti FVIII, XI, or XIII	1	0
Coagulopathies		
Disseminated intravascular coagulation	3	0
Eosinophilic disorders		
Eosinophilia	6	0
Leukocytoses NEC		
Monocytosis	1	0
Neutrophilia	3	0
Leukopenias NEC		
Lymphopenia	2	0
Lymphatic system disorders NEC		
Lymph node pain	17	0
Lymphadenopathy	142	0
Retroperitoneal lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	7	2
Pancytopenia	1	0
Neutropenias		
Agranulocytosis	1	1
Autoimmune neutropenia	2	0
Neutropenia	11	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	2	0
Spleen disorders		
Splenomegaly	1	0
Thrombocytopenias		
Immune thrombocytopenic purpura	24	0
Thrombocytopenia	22	0
Thrombocytopenic purpura	3	0
Thrombotic thrombocytopenic purpura	6	0
Thrombocytoses		
Thrombocytosis	3	0
Blood disorders SOC TOTAL	287	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block first degree	1	0
Conduction disorder	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	3	0
Cardiovascular disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	20	0
Palpitations	82	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
Stress cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	2	0
Coronary artery thrombosis	5	4
<i>Heart failures NEC</i>		
Cardiac failure	10	2
Cardiac failure acute	2	1
Cardiac failure congestive	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	1	0
Acute myocardial infarction	6	3
Angina pectoris	5	0
Myocardial infarction	31	13
Myocardial ischaemia	9	7
<i>Left ventricular failures</i>		
Left ventricular failure	9	2
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
Left ventricular hypertrophy	1	1
Ventricular hypertrophy	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	3	0
<i>Noninfectious pericarditis</i>		
Pericarditis	10	0
<i>Pericardial disorders NEC</i>		
Cardiac tamponade	1	0
Pericardial effusion	1	0
Pericardial haemorrhage	1	1
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	9	0
Bradycardia	10	0
Bradycardia foetal	1	0
Cardiac flutter	1	0
Extrasystoles	8	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	61	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	3	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0

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Cardiac disorders Cardiac disorders cont'd		
Atrial fibrillation	27	0
Atrial flutter	2	0
Sinus tachycardia	3	0
Supraventricular tachycardia	4	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	15	8
Cardio-respiratory arrest	1	1
Ventricular fibrillation	2	0
Ventricular flutter	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	366	44

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Ventricular septal defect	1	0
<i>Cerebral disorders congenital</i>		
Cerebral atrophy congenital	1	1
Dandy-Walker syndrome	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
Multiple congenital abnormalities	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>External ear disorders congenital</i>		
Accessory auricle	1	0
Low set ears	1	0
Microtia	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Talipes	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Plagiocephaly	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Hemivertebra	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital musculoskeletal anomaly	1	0
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Congenital neurological disorder	1	0
Spinal muscular atrophy	2	0
<i>Renal and urinary tract disorders congenital NEC</i>		
Urinary tract malformation	1	0
<i>Sex chromosomal abnormalities</i>		
Turner's syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	21	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	6	0
Ear discomfort	7	0
Ear disorder	1	0
Ear pain	43	0
Ear pruritus	2	0
Ear swelling	5	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>Hearing losses</i>		
Deafness	14	0
Deafness neurosensory	8	0
Deafness transitory	2	0
Deafness unilateral	13	0
Hypoacusis	14	0
Sudden hearing loss	2	0
<i>Hyperacusia</i>		
Hyperacusis	4	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	2	0
Meniere's disease	4	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	2	0
Tinnitus	32	0
Vertigo	65	0
Vertigo positional	4	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	234	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis subacute	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	2	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Hypothalamo-pituitary disorder	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
Thyroid mass	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	1	0
Thyrotoxic crisis	1	0
Endocrine disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Choroidal effusion	1	0
Vitreous detachment	1	0
Vitreous floaters	3	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	3	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	3	0
Conjunctival oedema	2	0
Conjunctivitis allergic	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	1	0
<i>Corneal structural change, deposit and degeneration</i>		
Keratic precipitates	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
Eyelid function disorder	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	5	0
Normal tension glaucoma	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
Iritis	1	0
Uveitis	2	0
<i>Lacrimation disorders</i>		
Dry eye	6	0
Lacrimal disorder	1	0
Lacrimation increased	17	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid irritation	1	0
Eyelid oedema	5	0
Swelling of eyelid	16	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid thickening	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	5	0
Eye pain	40	0
Eye swelling	56	0
Eyelid pain	2	0
Periorbital oedema	11	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	5	0
Eye inflammation	2	0
Eye irritation	9	0
Eye pruritus	15	0
Ocular hyperaemia	22	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	9	0
Ophthalmoplegia	2	0
<i>Ocular sensation disorders</i>		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Asthenopia	4	0
Foreign body sensation in eyes	2	0
Photophobia	21	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	2	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	6	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	2	0
<i>Pupil disorders</i>		
Mydriasis	2	0
Pupil fixed	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal detachment	1	0
Retinal tear	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Cystoid macular oedema	1	0
Retinal vasculitis	1	0
<i>Retinopathies NEC</i>		
Acute macular outer retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Scleritis	3	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual disorders NEC</i>		
Diplopia	14	0
Metamorphopsia	3	0
Photopsia	8	0
Vision blurred	47	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	9	0
Blindness transient	6	0
Blindness unilateral	1	0
Visual acuity reduced	4	0
Visual impairment	31	0
Eye disorders SOC TOTAL	431	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	4	0
Pancreatitis acute	5	0
Pancreatitis haemorrhagic	1	1
<i>Anal and rectal signs and symptoms</i>		
Anorectal discomfort	2	0
Perianal erythema	1	0
<i>Colitis (excl infective)</i>		
Colitis microscopic	1	0
Colitis ulcerative	2	0
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	1	0
Toothache	7	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	274	0
Diarrhoea haemorrhagic	2	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	12	0
Eructation	4	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	2	0
Faeces discoloured	5	0
Mucous stools	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	16	0
Flatulence	8	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	61	0
Abdominal pain lower	9	0
Abdominal pain upper	84	0
Abdominal rigidity	2	0
Abdominal tenderness	3	0
Gastrointestinal pain	3	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	10	0
Gastric dilatation	2	0
Gastrooesophageal reflux disease	4	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	3	0
Gastric disorder	1	0
Gastrointestinal disorder	7	0
Stomach mass	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	2	0
Dyschezia	1	0
Gastrointestinal motility disorder	4	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Vasculitis gastrointestinal	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	32	0
Anal incontinence	3	0
Dysphagia	40	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	2	0
Frequent bowel movements	2	0
Irritable bowel syndrome	6	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	3	0
Gingival swelling	1	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	4	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	5	0
<i>Nausea and vomiting symptoms</i>		
Nausea	471	0
Retching	5	0
Vomiting	397	0
Vomiting projectile	3	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	3	0
Haematochezia	1	0
Melaena	2	0
<i>Oesophageal ulcers and perforation</i>		
Oesophageal ulcer	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	28	0
Lip dry	1	0
Saliva altered	2	0
Salivary hypersecretion	4	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Cheilitis	1	0
Lip blister	2	0
Oral disorder	2	0
Oral lichen planus	2	0
Oral papule	1	0
Pigmentation lip	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	3	0
<i>Oral soft tissue pain and paraesthesia</i>		
Lip pain	3	0
Odynophagia	2	0
Oral pain	11	0
Paraesthesia oral	65	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	19	0
Lip discolouration	1	0
Lip erythema	4	0
Oral discomfort	5	0
Oral mucosal blistering	7	0
Oral mucosal eruption	1	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	1	0
Oral pruritus	3	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	1	0
Lip swelling	86	0
Mouth swelling	12	0
Oedema mouth	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	2	0
Submaxillary gland enlargement	1	0
<i>Salivary gland infections and inflammations</i>		
Salivary duct inflammation	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	2	0
Mouth ulceration	20	0
Stomatitis	7	0
<i>Tongue disorders</i>		
Glossitis	2	0
Plicated tongue	1	0
Tongue disorder	2	0
Tongue haemorrhage	1	0
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	2	0
Protrusion tongue	1	0
Swollen tongue	63	0
Tongue blistering	2	0
Tongue discolouration	1	0
Tongue discomfort	2	0
Tongue erythema	1	0
Tongue oedema	2	0
Gastrointestinal disorders SOC TOTAL	1930	1

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General disorders		
<i>Administration site reactions NEC</i>		
Administration site joint discomfort	1	0
Administration site joint pain	1	0
Administration site phlebitis	1	0
Administration site rash	1	0
Puncture site haemorrhage	1	0
<i>Adverse effect absent</i>		
No adverse event	7	0
<i>Application and instillation site reactions</i>		
Application site erythema	3	0
Application site inflammation	1	0
Application site pain	3	0
Application site pruritus	1	0
Application site rash	1	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	1	0
<i>Asthenic conditions</i>		
Asthenia	213	0
Chronic fatigue syndrome	8	0
Fatigue	470	0
Malaise	821	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	4	0
Temperature regulation disorder	1	0
<i>Complications associated with device NEC</i>		
Injury associated with device	3	0
<i>Death and sudden death</i>		
Death	19	19
Sudden death	33	33
<i>Febrile disorders</i>		
Hyperpyrexia	4	0
Pyrexia	761	0
<i>Feelings and sensations NEC</i>		
Chills	333	0
Feeling abnormal	75	0
Feeling cold	75	0
Feeling drunk	4	0
Feeling hot	179	0
Feeling jittery	2	0
Feeling of body temperature change	50	0
Hunger	2	0
Sensation of foreign body	7	0
Thirst	8	0
<i>Gait disturbances</i>		
Gait disturbance	35	0
Gait inability	11	0
Loss of control of legs	2	0
<i>General signs and symptoms NEC</i>		
Apparent death	2	0
Condition aggravated	42	1
Crepitations	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Crying	11	0
Deformity	1	0
Disease progression	1	0
Disease recurrence	1	0
Effusion	2	0
Exercise tolerance decreased	3	0
General physical health deterioration	2	0
Ill-defined disorder	5	0
Induration	14	0
Influenza like illness	476	0
Local reaction	104	0
Moaning	1	0
Multiple organ dysfunction syndrome	7	2
Peripheral swelling	287	0
Screaming	4	0
Secretion discharge	6	0
Swelling	204	0
Unevaluable event	2	0
Healing abnormal NEC		
Impaired healing	2	0
Inflamations		
Granuloma	25	0
Inflammation	83	0
Soft tissue inflammation	2	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site pain	1	0
Injection site reactions		
Injected limb mobility decreased	19	0
Injection site abscess sterile	1	0
Injection site atrophy	2	0
Injection site bruising	21	0
Injection site discharge	1	0
Injection site discolouration	3	0
Injection site discomfort	8	0
Injection site dryness	1	0
Injection site erythema	178	0
Injection site extravasation	1	0
Injection site fibrosis	1	0
Injection site haematoma	1	0
Injection site haemorrhage	8	0
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	4	0
Injection site induration	17	0
Injection site inflammation	79	0
Injection site irritation	3	0
Injection site joint erythema	1	0
Injection site joint movement impairment	1	0
Injection site joint pain	2	0
Injection site joint warmth	1	0
Injection site mass	42	0
Injection site movement impairment	7	0
Injection site necrosis	3	0

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General disorders General disorders cont'd		
Injection site oedema	3	0
Injection site pain	228	0
Injection site papule	1	0
Injection site pruritus	57	0
Injection site rash	35	0
Injection site reaction	237	0
Injection site scab	3	0
Injection site scar	3	0
Injection site swelling	113	0
Injection site ulcer	2	0
Injection site urticaria	10	0
Injection site vesicles	10	0
Injection site warmth	58	0
Interactions		
Alcohol interaction	1	0
Drug interaction	36	0
Food interaction	1	0
Inhibitory drug interaction	2	0
Potentiating drug interaction	4	0
Mass conditions NEC		
Mass	16	0
Mucosal findings abnormal		
Mucosal discolouration	1	0
Mucosal inflammation	2	0
Necrosis NEC		
Necrosis	3	0
Oedema NEC		
Face oedema	9	0
Generalised oedema	2	0
Gravitational oedema	1	0
Localised oedema	7	0
Oedema	21	0
Oedema peripheral	21	0
Pain and discomfort NEC		
Axillary pain	15	0
Chest discomfort	85	0
Chest pain	117	0
Discomfort	29	0
Facial pain	14	0
Non-cardiac chest pain	2	0
Pain	473	0
Tenderness	43	0
Therapeutic and nontherapeutic responses		
Adverse event	3	0
Adverse reaction	3	0
Drug ineffective	11	0
Immediate post-injection reaction	2	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	4	0
Trophic disorders		
Calcinosis	1	0
Hyperplasia	1	0
Ulcers NEC		

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Name: FOI 19-459 Inactivated Influenza DAP

Report Run Date: 08-Oct-2019
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 07-Oct-2019 19:00:04
 MedDRA Version: MedDRA 22.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Ulcer	2	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	3	0
Vaccination site atrophy	1	0
Vaccination site bruising	39	0
Vaccination site coldness	1	0
Vaccination site discolouration	6	0
Vaccination site discomfort	9	0
Vaccination site erythema	245	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	5	0
Vaccination site hypersensitivity	1	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	44	0
Vaccination site inflammation	48	0
Vaccination site irritation	2	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	3	0
Vaccination site joint pain	7	0
Vaccination site joint swelling	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	36	0
Vaccination site movement impairment	20	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site pain	275	0
Vaccination site papule	2	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	48	0
Vaccination site rash	36	0
Vaccination site reaction	21	0
Vaccination site scab	1	0
Vaccination site scar	1	0
Vaccination site swelling	221	0
Vaccination site urticaria	5	0
Vaccination site vesicles	3	0
Vaccination site warmth	102	0
General disorders SOC TOTAL	7738	55

Case Series Drug Analysis Print

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Report Run Date: 08-Oct-2019
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 07-Oct-2019 19:00:04
 MedDRA Version: MedDRA 22.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	2	0
Cholelithiasis	2	0
<i>Cholestasis and jaundice</i>		
Hepatitis cholestatic	1	0
Hyperbilirubinaemia neonatal	1	0
Jaundice	16	0
Jaundice cholestatic	2	0
Ocular icterus	1	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	2	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	6	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	1
Hepatic failure	1	0
Hepatorenal failure	1	0
Hepatorenal syndrome	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
Hepatomegaly	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Drug-induced liver injury	1	0
Hepatitis	10	0
Hepatitis acute	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	57	1

Case Series Drug Analysis Print

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Report Run Date: 08-Oct-2019
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 07-Oct-2019 19:00:04
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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	185	0
Serum sickness	2	0
Serum sickness-like reaction	5	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	2	0
Type IV hypersensitivity reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	1	0
Allergy to chemicals	1	0
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
Food allergy	4	0
Reaction to excipient	7	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	185	1
Anaphylactic shock	21	1
Anaphylactoid reaction	22	0
<i>Atopic disorders</i>		
Seasonal allergy	3	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	4	0
<i>Immune and associated conditions NEC</i>		
Decreased immune responsiveness	1	0
Graft versus host disease	1	0
Haemophagocytic lymphohistiocytosis	2	2
Immune system disorder	7	0
Sensitisation	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	2	0
<i>Transplant rejections</i>		
Corneal graft rejection	4	0
Kidney transplant rejection	1	0
<i>Vasculitides</i>		
Anti-neutrophil cytoplasmic antibody positive vasculitis	3	0
Eosinophilic granulomatosis with polyangiitis	3	0
Immune system disorders SOC TOTAL	474	4

Case Series Drug Analysis Print

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Report Run Date: 08-Oct-2019
Earliest Reaction Date: 09-Oct-1963

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diarrhoea infectious	1	0
Diverticulitis	1	0
Gastroenteritis	4	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	4	0
Arthritis bacterial	1	0
Bacterial infection	1	0
Cellulitis	63	0
Gangrene	4	1
Injection site cellulitis	13	0
Pneumonia bacterial	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	17	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
Intervertebral discitis	2	0
<i>Borrelial infections</i>		
Lyme disease	1	0
<i>Breast infections</i>		
Mastitis	1	0
<i>Candida infections</i>		
Candida infection	4	0
Oral candidiasis	1	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	28	3
Encephalomyelitis	9	1
Meningitis	4	1
Myelitis	4	0
Panencephalitis	1	0
<i>Clostridia infections</i>		
Gas gangrene	1	1
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
<i>Dental and oral soft tissue infections</i>		
Parotitis	2	0
<i>Ear infections</i>		
Ear infection	6	0
Labyrinthitis	16	0
Otitis media	2	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	20	0
Hordeolum	1	0
<i>Female reproductive tract infections</i>		
Amniotic cavity infection	2	0
<i>Flaviviral infections</i>		
Yellow fever vaccine-associated neurotropic disease	1	0
<i>Fungal infections NEC</i>		
Ear infection fungal	1	0

Case Series Drug Analysis Print

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Report Run Date: 08-Oct-2019
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Reaction Name	Total	Fatal
Infections Infections cont'd		
Fungal skin infection	1	0
Haemophilus infections		
Haemophilus infection	1	0
Haemophilus sepsis	1	0
Pneumonia haemophilus	1	0
Septic arthritis haemophilus	1	0
Hepatitis viral infections		
Gianotti-Crosti syndrome	1	0
Hepatobiliary and spleen infections		
Liver abscess	1	0
Herpes viral infections		
Herpes ophthalmic	1	0
Herpes simplex	8	0
Herpes simplex encephalitis	1	0
Herpes virus infection	1	0
Herpes zoster	55	0
Herpes zoster meningitis	1	0
Herpes zoster oticus	1	0
Ophthalmic herpes zoster	6	0
Oral herpes	23	0
Varicella	3	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	10	0
Abscess limb	2	0
Device related infection	1	0
Infection	17	0
Injection site abscess	9	0
Injection site infection	10	0
Localised infection	6	0
Purulence	1	0
Purulent discharge	1	0
Respiratory tract infection	3	0
Toxic shock syndrome	1	0
Vaccination site abscess	1	0
Vaccination site infection	7	0
Vaccine breakthrough infection	1	0
Infectious transmissions		
Infection via vaccinee	2	0
Nosocomial infection	1	0
Suspected transmission of an infectious agent via product	1	0
Influenza viral infections		
H1N1 influenza	12	0
Influenza	137	1
Pneumonia influenzal	3	0
Lower respiratory tract and lung infections		
Atypical pneumonia	2	0
Bronchitis	33	0
Infective exacerbation of chronic obstructive airways disease	4	0
Lower respiratory tract infection	114	0
Lung infection	1	0
Pneumonia	69	16
Sputum purulent	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Muscle and soft tissue infections</i>		
Soft tissue infection	2	0
<i>Neisseria infections</i>		
Meningococcal sepsis	1	1
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	3	1
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Sepsis	22	4
Septic shock	1	0
Urosepsis	1	0
Viraemia	1	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
Folliculitis	2	0
Impetigo	1	0
Injection site pustule	1	0
Rash pustular	4	0
Skin infection	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
Staphylococcal infection	1	0
<i>Streptococcal infections</i>		
Streptococcal abscess	1	0
Streptococcal infection	3	0
<i>Tinea infections</i>		
Malassezia infection	1	0
<i>Tuberculous infections</i>		
Erythema induratum	13	0
<i>Upper respiratory tract infections</i>		
Laryngitis	11	0
Nasopharyngitis	130	0
Pharyngitis	12	0
Rhinitis	22	0
Sinusitis	21	0
Tonsillitis	1	0
Upper respiratory tract infection	31	0
<i>Urinary tract infections</i>		
Cystitis	5	0
Kidney infection	1	0
Pyelonephritis	2	0
Urinary tract infection	11	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Encephalitis viral	6	0
Meningitis viral	2	0
Pneumonia viral	1	0
Post viral fatigue syndrome	16	0
Sweating fever	2	0

Case Series Drug Analysis Print

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Report Run Date: 08-Oct-2019

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Earliest Reaction Date: 09-Oct-1963

MedDRA Version: MedDRA 22.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Vestibular neuronitis	7	0
Viral infection	14	0
Viral labyrinthitis	1	0
Viral myocarditis	1	0
Viral rash	5	0
Viral upper respiratory tract infection	12	0
Infections SOC TOTAL	1161	30

Case Series Drug Analysis Print

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Report Run Date: 08-Oct-2019
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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
Chest injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	26	0
Foetal exposure during pregnancy	14	0
Maternal exposure before pregnancy	1	0
Maternal exposure during pregnancy	13	0
Maternal exposure timing unspecified	2	0
<i>Eye injuries NEC</i>		
Retinal injury	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Device difficult to use	1	0
Medication error	5	0
Product use issue	2	0
Vaccination error	1	0
Wrong technique in product usage process	4	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	2	0
Muscle injury	4	0
Muscle rupture	1	0
Muscle strain	1	0
Tendon injury	1	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	13	0
<i>Non-site specific injuries NEC</i>		
Eschar	1	0
Fall	23	0
Injury	4	0
Wound	2	0
Wound haemorrhage	1	0
Wound secretion	1	0
<i>Non-site specific procedural complications</i>		
Procedural pain	1	0
Wound decomposition	1	0
Wound dehiscence	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Peripheral nerve injuries</i>		
Axillary nerve injury	1	0
Ulnar nerve injury	1	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	1	0
Toxicity to various agents	2	1
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Contraindicated product administered	3	0
Expired product administered	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Extra dose administered	8	0
Inappropriate schedule of product administration	5	0
Incorrect dose administered	5	0
Incorrect route of product administration	2	0
Product administered at inappropriate site	17	0
Product administered to patient of inappropriate age	30	0
Product administration error	8	0
Wrong product administered	4	0
<i>Product monitoring errors and issues</i>		
Labelled drug-drug interaction medication error	1	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	2	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	1	0
<i>Site specific injuries NEC</i>		
Face injury	2	0
Head injury	7	0
Limb injury	2	0
Tooth injury	1	0
<i>Skin injuries NEC</i>		
Contusion	60	0
Scar	3	0
Skin abrasion	1	0
Skin laceration	6	0
<i>Thermal burns</i>		
Thermal burn	1	0
<i>Vaccination related complications</i>		
Vaccination complication	2	0
Vaccination failure	24	0
Injuries SOC TOTAL	339	1

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Anti-glomerular basement membrane antibody positive	1	0
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Antiphospholipid antibodies positive	1	0
DNA antibody positive	1	0
Rheumatoid factor increased	1	0
<i>Blood counts NEC</i>		
Blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Blood gases abnormal	1	0
Blood lactic acid decreased	1	0
Carbon dioxide decreased	1	0
Oxygen saturation decreased	8	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose abnormal	1	0
Blood glucose decreased	4	0
Blood glucose fluctuation	3	0
Blood glucose increased	4	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Cell marker analyses</i>		
HLA marker study positive	1	0
<i>Central nervous system imaging procedures</i>		
Nuclear magnetic resonance imaging brain abnormal	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF protein increased	3	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	5	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	1	0
High density lipoprotein decreased	1	0
<i>Coagulation and bleeding analyses</i>		
Activated partial thromboplastin time prolonged	1	0
Bleeding time prolonged	2	0
Coagulation time prolonged	3	0
Fibrin D dimer increased	1	0
International normalised ratio abnormal	2	0
International normalised ratio decreased	4	0
International normalised ratio increased	31	0
Prothrombin time shortened	1	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
<i>ECG investigations</i>		
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment depression	1	0
Electrocardiogram abnormal	1	0
Electrocardiogram change	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	17	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate decreased	9	0
Heart rate increased	47	0
Heart rate irregular	10	0
Pulse abnormal	2	0
Imaging procedures NEC		
Computerised tomogram abnormal	2	0
Optical coherence tomography abnormal	1	0
Positron emission tomogram abnormal	1	0
Ultrasound scan abnormal	2	0
Immune response protein analyses NEC		
Complement factor C3 increased	1	0
Investigations NEC		
Blood test abnormal	2	0
False positive investigation result	1	0
Quality of life decreased	2	0
Liver function analyses		
Alanine aminotransferase increased	6	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	5	0
Liver function test abnormal	17	0
Liver function test increased	3	0
Metabolism tests NEC		
Blood ketone body increased	1	0
Microbiology and serology tests NEC		
Blood culture negative	1	0
Mineral and electrolyte analyses		
Blood calcium increased	1	0
Blood iron decreased	1	0
Blood phosphorus increased	1	0
Blood potassium decreased	1	0
Blood sodium abnormal	1	0
Blood sodium decreased	4	0
Musculoskeletal and soft tissue imaging procedures		
Spinal X-ray abnormal	1	0
Neurologic diagnostic procedures		
Electroencephalogram abnormal	2	0
Nerve conduction studies abnormal	1	0
Romberg test positive	1	0
Sensory level abnormal	2	0
Sleep study abnormal	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	2	0
Physical examination procedures and organ system status		
Body temperature	1	0
Body temperature abnormal	2	0
Body temperature decreased	3	0
Body temperature fluctuation	4	0
Body temperature increased	75	0
Breath sounds abnormal	2	0
Grip strength decreased	7	0
Respiratory rate decreased	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Respiratory rate increased	5	0
Weight decreased	12	0
Weight increased	3	0
Platelet analyses		
Platelet count decreased	8	0
Platelet count increased	1	0
Protein analyses NEC		
C-reactive protein abnormal	1	0
C-reactive protein increased	14	0
Globulins increased	1	0
Protein total increased	1	0
Red blood cell analyses		
Haemoglobin abnormal	1	0
Haemoglobin decreased	3	0
Haemoglobin increased	1	0
Mean cell volume increased	1	0
Renal function analyses		
Blood creatinine increased	4	0
Blood urea increased	3	0
Creatinine renal clearance decreased	1	0
Glomerular filtration rate decreased	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Peak expiratory flow rate decreased	5	0
Pulmonary function test decreased	2	0
Vital capacity decreased	1	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray abnormal	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	4	0
Skin histopathology procedures		
Biopsy skin abnormal	1	0
Thyroid analyses		
Thyroid function test abnormal	1	0
Thyroxine increased	1	0
Thyroid histopathology procedures		
Biopsy thyroid gland abnormal	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	3	0
Urinalysis NEC		
Blood urine present	7	0
Glucose urine present	1	0
Protein urine present	2	0
Urine analysis	2	0
Urine analysis abnormal	1	0
Urinary tract function analyses NEC		
Urine output decreased	3	0
Urinary tract histopathology procedures		
Biopsy kidney abnormal	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	16	0
Blood pressure diastolic increased	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure increased	31	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Cytomegalovirus test positive	1	0
Epstein-Barr virus antibody positive	2	0
Influenza A virus test positive	1	0
<i>White blood cell analyses</i>		
Lymphocyte count decreased	3	0
Lymphocyte morphology abnormal	1	0
Neutrophil count decreased	4	0
Neutrophil count increased	2	0
White blood cell count decreased	4	0
White blood cell count increased	7	0
Investigations SOC TOTAL	518	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	122	0
Hypophagia	7	0
<i>Cell metabolism disorders NEC</i>		
Mitochondrial cytopathy	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	4	0
Diabetes mellitus inadequate control	5	0
Type 1 diabetes mellitus	4	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	5	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Fluid intake increased</i>		
Polydipsia	2	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	11	0
Feeding disorder	6	0
Food aversion	1	0
Poor feeding infant	1	0
Starvation	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	12	1
Hypoglycaemia neonatal	2	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Hyperlactacidaemia	1	0
Ketoacidosis	5	0
Metabolic acidosis	4	0
<i>Mixed acid-base disorders</i>		
Acidosis	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	2	0
<i>Total fluid volume decreased</i>		
Dehydration	7	0
<i>Total fluid volume increased</i>		
Fluid retention	3	0
Metabolic disorders SOC TOTAL	218	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	46	0
Arthritis allergic	1	0
Arthritis reactive	12	0
Arthropathy	19	0
Haemarthrosis	2	0
Palindromic rheumatism	1	0
Polyarthrits	9	0
Seronegative arthritis	3	0
<i>Bone disorders NEC</i>		
Bone disorder	1	0
Exostosis	1	0
Jaw disorder	3	0
Osteitis	2	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	9	0
Pain in jaw	13	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	28	0
<i>Cartilage disorders</i>		
Costochondritis	2	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	1	0
Polymyalgia rheumatica	34	0
<i>Extremity deformities</i>		
Finger deformity	2	0
Hand deformity	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc degeneration	1	0
Intervertebral disc disorder	3	0
Intervertebral disc space narrowing	1	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
Periarthritis	38	0
Rotator cuff syndrome	4	0
<i>Joint related signs and symptoms</i>		
Arthralgia	366	0
Joint effusion	5	0
Joint noise	4	0
Joint range of motion decreased	7	0
Joint stiffness	26	0
Joint swelling	60	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Myositis	17	0
Myositis-like syndrome	1	0
<i>Muscle pains</i>		
Fibromyalgia	5	0
Myalgia	554	0
<i>Muscle related signs and symptoms NEC</i>		

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Report Run Date: 08-Oct-2019
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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle atrophy	11	0
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	3	0
Muscle mass	1	0
Muscle spasms	67	0
Muscle swelling	3	0
Muscle tightness	12	0
Muscle twitching	15	0
Neuropathic muscular atrophy	1	0
Muscle tone abnormalities		
Muscle rigidity	7	0
Torticollis	1	0
Muscle weakness conditions		
Muscular weakness	155	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	2	0
Mobility decreased	20	0
Musculoskeletal disorder	2	0
Musculoskeletal stiffness	148	0
Posture abnormal	1	0
Weight bearing difficulty	2	0
Winged scapula	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dupuytren's contracture	1	0
Fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	106	0
Flank pain	2	0
Limb discomfort	58	0
Musculoskeletal chest pain	12	0
Musculoskeletal discomfort	14	0
Musculoskeletal pain	170	0
Neck pain	130	0
Pain in extremity	629	0
Rheumatic disorder	3	0
Myopathies		
Diabetic amyotrophy	1	0
Muscle necrosis	1	0
Myopathy	5	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Osteoarthritis	9	0
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	4	0
Rheumatoid arthropathies		
Rheumatoid arthritis	39	0
Soft tissue disorders NEC		
Axillary mass	3	0
Groin pain	3	0
Neck mass	3	0
Soft tissue swelling	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	2	0
<i>Synovial disorders</i>		
Synovitis	3	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon disorder	8	0
Tendon pain	2	0
Tendonitis	6	0
Tenosynovitis	2	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	2978	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leiomyosarcomas</i>		
Leiomyosarcoma	1	0
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	2	2
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	1
<i>Paranasal sinus and nasal cavity neoplasms malignant and unspecified</i>		
Nasal sinus cancer	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Placental chorioangioma	1	0
<i>Respiratory tract and pleural neoplasms malignancy unspecified NEC</i>		
Lung neoplasm	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	1	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Fibrous histiocytoma	1	0
Seborrhoeic keratosis	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	3	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Urinary tract neoplasms unspecified malignancy NEC</i>		
Renal neoplasm	1	0
Neoplasms SOC TOTAL	20	3

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	8	0
Hyperreflexia	1	0
Hyporeflexia	3	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	4	0
<i>Acute polyneuropathies</i>		
Acute polyneuropathy	1	0
Guillain-Barre syndrome	168	9
Miller Fisher syndrome	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic failure syndrome	1	0
Horner's syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basilar artery thrombosis	1	1
Brain stem haemorrhage	1	0
Cerebellar haemorrhage	1	0
Cerebellar infarction	1	1
Cerebral haemorrhage	4	3
Cerebral infarction	5	2
Cerebrovascular accident	31	4
Ischaemic stroke	2	0
Lacunar infarction	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebrovascular disorder	3	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	7	0
Demyelinating polyneuropathy	5	0
Diabetic neuropathy	2	0
<i>Coma states</i>		
Coma	9	0
Hypoglycaemic coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	13	0
Balance disorder	50	0
Coordination abnormal	5	0
Dysstasia	12	0
Nystagmus	6	0
<i>Cortical dysfunction NEC</i>		
Aphasia	23	0
Dysgraphia	1	0
Dyspraxia	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	3	0
Vascular dementia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	14	2
Demyelination	4	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	4	0
Consciousness fluctuating	1	0
Depressed level of consciousness	7	0
Lethargy	125	0
Loss of consciousness	85	1
Postictal state	1	0
Sedation	1	0
Somnolence	79	0
Stupor	3	0
Syncope	214	0
<i>Disturbances in sleep phase rhythm</i>		
Irregular sleep wake rhythm disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	1	0
Clumsiness	4	0
Dyskinesia	15	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	1	0
Hypokinesia	14	0
Motor dysfunction	3	0
Movement disorder	9	0
Up and down phenomenon	1	0
<i>Dystonias</i>		
Dystonia	2	0
<i>Encephalitis NEC</i>		
Bickerstaff's encephalitis	1	0
Encephalitis post immunisation	1	0
Noninfective encephalitis	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	11	0
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
IIIrd nerve paralysis	1	0
IVth nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	57	0
Facial paresis	8	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	26	0
<i>Headaches NEC</i>		
Cluster headache	2	0
Cold-stimulus headache	1	0
Headache	817	0
Sinus headache	2	0
Tension headache	8	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Intracranial pressure increased	2	1
Intellectual disabilities		
Intellectual disability	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	5	0
Memory loss (excl dementia)		
Amnesia	16	0
Memory impairment	11	0
Transient global amnesia	6	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	6	0
Disturbance in attention	17	0
Mental impairment	5	0
Migraine headaches		
Hemiplegic migraine	1	0
Migraine	46	0
Migraine with aura	6	0
Mononeuropathies		
Carpal tunnel syndrome	2	0
Mononeuropathy multiplex	4	0
Nerve compression	1	0
Peroneal nerve palsy	2	0
Radial nerve palsy	5	0
Ulnar neuritis	1	0
Motor neurone diseases		
Motor neurone disease	1	1
Multiple sclerosis acute and progressive		
Multiple sclerosis	11	0
Multiple sclerosis relapse	2	0
Muscle tone abnormal		
Hypertonia	2	0
Hypotonia	7	0
Myelitis (incl infective)		
Myelitis transverse	22	1
Narcolepsy and hypersomnia		
Cataplexy	5	0
Hypersomnia	14	0
Narcolepsy	16	0
Nervous system disorders NEC		
Brain stem syndrome	1	0
Cerebral disorder	1	0
Nervous system disorder	8	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	1	0
Tunnel vision	2	0
Visual field defect	10	0
Neurological signs and symptoms NEC		
Clonus	1	0
Dizziness	547	0
Dizziness exertional	1	0
Dizziness postural	7	0
Droling	2	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Head discomfort	18	0
Meningism	11	0
Myoclonus	1	0
Neurological symptom	7	0
Presyncope	18	0
Tongue biting	1	0
Unresponsive to stimuli	15	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	2	0
Olfactory nerve disorders		
Anosmia	9	0
Hyposmia	1	0
Parosmia	7	0
Optic nerve disorders NEC		
Optic neuritis	11	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning sensation	52	0
Dysaesthesia	2	0
Formication	2	0
Hyperaesthesia	18	0
Hypoaesthesia	189	0
Paraesthesia	387	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	10	0
Hemiplegia	11	1
Monoparesis	3	0
Monoplegia	10	0
Paralysis	26	0
Paraparesis	3	0
Paraplegia	7	0
Quadriparesis	1	0
Parkinson's disease and parkinsonism		
Cogwheel rigidity	1	0
Freezing phenomenon	1	0
Parkinson's disease	3	0
Reduced facial expression	1	0
Partial complex seizures		
Focal dyscognitive seizures	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	4	0
Brachial plexopathy	4	0
Lumbosacral plexopathy	1	0
Neuralgic amyotrophy	12	0
Neuritis	8	0
Neuropathy peripheral	38	0
Peripheral motor neuropathy	3	0
Peripheral sensorimotor neuropathy	2	0
Peripheral sensory neuropathy	6	0
Polyneuropathy	5	0
Seizures and seizure disorders NEC		
Convulsive threshold lowered	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Epilepsy	32	1
Epileptic aura	1	0
Febrile convulsion	7	0
Hypoglycaemic seizure	1	0
Myoclonic epilepsy	1	0
Neonatal seizure	1	0
Partial seizures	4	0
Seizure	78	0
Seizure like phenomena	3	0
Status epilepticus	2	0
Tonic clonic movements	1	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Ageusia	12	0
Allodynia	1	0
Aura	1	0
Dysgeusia	28	0
Hypogeusia	1	0
Loss of proprioception	2	0
Neuralgia	45	0
Post herpetic neuralgia	1	0
Restless legs syndrome	4	0
Sensory disturbance	21	0
Sensory loss	19	0
Taste disorder	14	0
Sleep disturbances NEC		
Poor quality sleep	2	0
Speech and language abnormalities		
Aphonia	20	0
Dysarthria	26	0
Incoherent	1	0
Speech disorder	12	0
Spinal cord and nerve root disorders NEC		
Brown-Sequard syndrome	1	0
Myelopathy	4	0
Radiculitis brachial	18	0
Radiculopathy	2	0
Spinal cord disorder	2	0
Spinal cord oedema	1	0
Structural brain disorders NEC		
Brain injury	3	0
Cerebral ventricle dilatation	1	0
Transient cerebrovascular events		
Transient ischaemic attack	7	0
Tremor (excl congenital)		
Essential tremor	1	0
Head titubation	1	0
Tremor	133	0
Trigeminal disorders		
Facial neuralgia	3	0
Trigeminal neuralgia	3	0
Vagus nerve disorders		
Paralysis recurrent laryngeal nerve	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Vocal cord paralysis	1	0
Nervous system disorders SOC TOTAL	4155	28

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	40	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	5	0
Foetal hypokinesia	2	0
<i>Foetal growth complications</i>		
Foetal growth restriction	3	0
<i>Gestational age and weight conditions</i>		
Premature baby	8	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	2	0
Premature separation of placenta	2	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	2	0
Premature labour	3	0
Premature rupture of membranes	1	0
Prolonged labour	3	0
<i>Maternal complications of delivery NEC</i>		
Breech delivery	1	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	1	0
Preterm premature rupture of membranes	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal newborn status</i>		
Normal newborn	3	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Uterine contractions during pregnancy	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	2	2
Stillbirth	9	9
Pregnancy conditions SOC TOTAL	93	11

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device loosening	1	0
<i>Device physical property and chemical issues</i>		
Needle issue	2	0
Syringe issue	2	0
<i>Product contamination and sterility issues</i>		
Product contamination	1	0
<i>Product label issues</i>		
Product lot number issue	1	0
<i>Product physical issues</i>		
Product colour issue	1	0
<i>Product quality issues NEC</i>		
Product quality issue	1	0
null SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	1	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
<i>Anxiety symptoms</i>		
Agitation	17	0
Anxiety	42	0
Nervousness	9	0
Stress	3	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	4	0
Aversion	1	0
Paranoia	1	0
Personality change	1	0
Social avoidant behaviour	2	0
<i>Brief psychotic disorder</i>		
Brief psychotic disorder with marked stressors	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
<i>Confusion and disorientation</i>		
Confusional state	79	0
Disorientation	31	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	7	0
<i>Depressive disorders</i>		
Depression	29	0
Depression suicidal	1	0
<i>Dissociative states</i>		
Dissociation	3	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	61	0
Middle insomnia	1	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
Eating disorder	4	0
<i>Emotional and mood disturbances NEC</i>		
Anger	3	0
Emotional disorder	2	0
Emotional distress	5	0
Irritability	11	0
Mood altered	5	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	5	0
Phobia	1	0
Phonophobia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Fluctuating mood symptoms</i>		
Mood swings	3	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	16	0
Hallucination, visual	3	0
<i>Increased physical activity levels</i>		
Restlessness	5	0
<i>Learning disorders</i>		
Learning disorder	1	0
Reading disorder	1	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	1	0
Depressed mood	16	0
Feeling of despair	3	0
Feelings of worthlessness	1	0
Negative thoughts	2	0
Tearfulness	11	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
<i>Mood disorders NEC</i>		
Apathy	2	0
Listless	11	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive disorder	1	0
<i>Panic attacks and disorders</i>		
Panic attack	11	0
Panic reaction	5	0
<i>Parasomnias</i>		
Abnormal dreams	6	0
Nightmare	9	0
Sleep talking	2	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Deja vu	1	0
Derealisation	2	0
Illusion	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	3	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Psychotic disorder NEC</i>		
Postictal psychosis	1	0
Psychotic disorder	5	0
<i>Sexual desire disorders</i>		
Loss of libido	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	22	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Stereotypies and automatisms</i>		
Bruxism	1	0
Head banging	1	0
<i>Substance related and addictive disorders</i>		
Alcoholic hangover	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	2	2
Intentional self-injury	1	0
Suicidal ideation	4	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	2	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	511	2

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Dysuria	7	0
Incontinence	9	0
Micturition urgency	3	0
Pollakiuria	5	0
Urinary incontinence	7	0
Urinary retention	6	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Bladder obstruction	1	0
Urinary bladder haemorrhage	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis acute	1	1
IgA nephropathy	1	0
Nephrotic syndrome	5	0
<i>Myoneurogenic bladder disorders</i>		
Neurogenic bladder	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Fanconi syndrome acquired	2	0
Renal tubular dysfunction	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
Renal haemorrhage	1	0
Single functional kidney	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	27	0
Anuria	2	0
Chronic kidney disease	2	0
Oliguria	2	0
Renal failure	7	0
Renal impairment	7	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal tubular injury	1	0
Renal vasculitis	2	0
<i>Urinary abnormalities</i>		
Chromaturia	5	0
Haematuria	6	1
Ketonuria	2	0
Myoglobinuria	1	0
Proteinuria	2	0
Urine abnormality	3	0
<i>Urinary tract lithiasis (excl renal)</i>		
Ureterolithiasis	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Polyuria	2	0
Renal pain	9	0

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Earliest Reaction Date: 09-Oct-1963

MedDRA Version: MedDRA 22.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	142	2

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Report Run Date: 08-Oct-2019
Earliest Reaction Date: 09-Oct-1963

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	6	0
Breast swelling	2	0
Breast tenderness	1	0
Nipple swelling	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstrual disorder	2	0
Metrorrhagia	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	1	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penis disorder	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic disorder	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital discomfort	1	0
Genital rash	1	0
Pelvic pain	1	0
Pruritus genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal disorder	1	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
Semen discolouration	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	8	0
Vulval ulceration	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal burning sensation	1	0
Vulvovaginal pain	1	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	40	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	3	0
Dyspnoea	282	0
Dyspnoea exertional	4	0
Hyperventilation	7	0
Hypopnoea	3	0
Irregular breathing	1	0
Respiration abnormal	3	0
Respiratory arrest	9	0
Respiratory depression	1	0
Respiratory distress	8	0
Sleep apnoea syndrome	1	0
Tachypnoea	3	0
<i>Bronchial conditions NEC</i>		
Bronchomalacia	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	112	1
Asthma exercise induced	1	0
Bronchospasm	29	0
Chronic obstructive pulmonary disease	15	3
Obstructive airways disorder	1	0
Status asthmaticus	2	1
Wheezing	88	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	2
Cyanosis central	1	0
Hypoxia	4	0
Respiratory gas exchange disorder	1	0
<i>Coughing and associated symptoms</i>		
Cough	314	0
Haemoptysis	6	0
Productive cough	51	0
Sputum discoloured	3	0
Sputum increased	4	0
Sputum retention	1	0
<i>Diaphragmatic disorders</i>		
Diaphragm muscle weakness	1	0
Diaphragmatic disorder	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Vocal cord dysfunction	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	2	0
Stridor	4	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Mendelson's syndrome	1	0
Pneumonia aspiration	5	2
Pneumonitis	5	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
Increased bronchial secretion	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pleuritic pain	4	0
Pulmonary pain	1	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	47	0
Rhinitis perennial	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	25	0
Nasal dryness	1	0
Nasal mucosal erosion	1	0
Nasal odour	1	0
Nasal oedema	1	0
Nasal pruritus	1	0
Nasal ulcer	1	0
<i>Neonatal hypoxic conditions</i>		
Neonatal respiratory distress	1	0
<i>Newborn respiratory disorders NEC</i>		
Bronchopulmonary dysplasia	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	2	0
Sinus congestion	7	0
Sinus disorder	11	0
<i>Parenchymal lung disorders NEC</i>		
Idiopathic pulmonary fibrosis	2	0
Interstitial lung disease	1	0
Lung consolidation	1	0
Lung infiltration	1	0
Organising pneumonia	1	0
Pulmonary fibrosis	13	3
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal disorder	2	0
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	39	0
Tonsillar disorder	3	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	3	0
Pneumothorax	2	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Acute respiratory distress syndrome	2	0
Pulmonary congestion	1	0
Pulmonary oedema	6	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	10	6
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	0
Respiratory failure	20	4
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	5	0
Respiratory symptom	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Lung disorder	4	0
Respiratory disorder	10	0
Respiratory tract congestion	6	0
Respiratory tract inflammation	1	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal oedema	1	0
Tracheomalacia	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Catarrh	19	0
Choking	6	0
Choking sensation	5	0
Dry throat	12	0
Dysphonia	27	0
Increased viscosity of upper respiratory secretion	1	0
Laryngeal pain	3	0
Nasal discomfort	7	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	236	0
Rhinalgia	1	0
Rhinorrhoea	112	0
Sinus pain	8	0
Sneezing	50	0
Snoring	1	0
Throat irritation	22	0
Throat tightness	48	0
Upper-airway cough syndrome	5	0
Yawning	3	0
Respiratory disorders SOC TOTAL	1813	22

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	3	0
<i>Alopecias</i>		
Alopecia	7	0
Alopecia areata	2	0
Madarosis	2	0
<i>Angioedemas</i>		
Angioedema	41	0
Circumoral oedema	1	0
Swelling face	114	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	58	0
Hyperhidrosis	249	0
Miliaria	2	0
Night sweats	27	0
<i>Bullous conditions</i>		
Blister	48	0
Blood blister	5	0
Dermatitis bullous	2	0
Erythema multiforme	30	0
Pemphigoid	9	0
Pemphigus	1	0
Stevens-Johnson syndrome	5	0
Toxic epidermal necrolysis	1	0
<i>Connective tissue disorders</i>		
Dermatomyositis	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dermatosis	1	0
Dry skin	19	0
Macule	2	0
Pain of skin	10	0
Papule	9	0
Scab	3	0
Sensitive skin	1	0
Skin burning sensation	10	0
Skin discolouration	16	0
Skin discomfort	1	0
Skin disorder	6	0
Skin fissures	2	0
Skin induration	8	0
Skin lesion	13	0
Skin necrosis	1	0
Skin reaction	35	0
Skin sensitisation	2	0
Skin swelling	3	0
Skin texture abnormal	3	0
Skin tightness	8	0
Skin warm	89	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	13	0
Dermatitis allergic	40	0
Dermatitis contact	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Eczema	27	0
Seborrhoeic dermatitis	5	0
Skin irritation	18	0
Stasis dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	3	0
Drug reaction with eosinophilia and systemic symptoms	2	0
Toxic skin eruption	3	0
<i>Erythemas</i>		
Erythema	410	0
Generalised erythema	3	0
Palmar erythema	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	3	0
Dermatitis exfoliative generalised	3	0
Skin exfoliation	31	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma skin	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	6	0
Panniculitis	1	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen planus	5	0
Parapsoriasis	1	0
Pityriasis rosea	7	0
Rash papulosquamous	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	7	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Hair colour changes	1	0
Piloerection	1	0
<i>Pruritus NEC</i>		
Itching scar	1	0
Pruritus	340	0
Pruritus generalised	42	0
Rash pruritic	79	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	1	0
Erythrodermic psoriasis	1	0
Guttate psoriasis	3	0
Psoriasis	9	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	15	0
Petechiae	11	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Purpura	28	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	2	0
Rash follicular	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	281	0
Rash erythematous	104	0
Rash generalised	98	0
Rash macular	51	0
Rash maculo-papular	37	0
Rash morbilliform	3	0
Rash papular	33	0
Rash vesicular	9	0
<i>Rosaceas</i>		
Rosacea	1	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Eosinophilic cellulitis	1	0
Skin mass	4	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Pyoderma gangrenosum	1	0
Skin ulcer	4	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Skin dystrophies</i>		
Keloid scar	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	3	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	1	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	2	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	7	0
Hypersensitivity vasculitis	10	0
Vasculitic rash	10	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	3	0
<i>Urticarias</i>		
Cold urticaria	1	0
Idiopathic urticaria	2	0
Mechanical urticaria	1	0
Urticaria	311	0
Urticaria chronic	1	0
Urticaria papular	3	0
Urticarial vasculitis	5	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin disorders SOC TOTAL	2983	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	9	0
Disability	1	0
Hearing disability	1	0
Housebound	1	0
Immobile	1	0
Impaired driving ability	1	0
Impaired work ability	3	0
Loss of personal independence in daily activities	16	0
Physical disability	1	0
Walking aid user	1	0
Walking disability	1	0
Wheelchair user	1	0
<i>Employment issues</i>		
Stress at work	1	0
<i>Social issues NEC</i>		
Contraindication to vaccination	2	0
Impaired quality of life	1	0
Social circumstances SOC TOTAL	41	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Nerve block	2	0
<i>Blood and blood product treatment</i>		
Plasmapheresis	1	0
<i>Large intestine therapeutic procedures</i>		
Colon operation	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	2	0
Episiotomy	1	0
Forceps delivery	1	0
Vacuum extractor delivery	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	2	0
Resuscitation	1	0
<i>Urethral therapeutic procedures</i>		
Urethrotomy	1	0
Surgical & medical procedures SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	3	0
Aortic aneurysm rupture	1	1
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Arterial infections and inflammations</i>		
Temporal arteritis	5	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	2	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	29	2
Neurogenic shock	1	0
Peripheral circulatory failure	1	0
Shock	4	0
Shock symptom	1	0
<i>Haemorrhages NEC</i>		
Haematoma	6	0
Haemorrhage	17	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	6	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Infarction	1	0
Ischaemia	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
Vasodilatation	2	0
Vein disorder	1	0
Vein rupture	1	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	1
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	5	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	66	0
Hot flush	25	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Intermittent claudication	1	0
Peripheral coldness	17	0
Peripheral ischaemia	2	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	1	0
<i>Phlebitis NEC</i>		
Phlebitis	3	0
<i>Site specific vascular disorders NEC</i>		
Aortic dilatation	1	0
Pallor	73	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	52	0
<i>Vascular hypotensive disorders</i>		
Hypotension	37	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Vasculitides NEC</i>		
Behcet's syndrome	1	0
Cryoglobulinaemia	1	0
Granulomatosis with polyangiitis	4	0
Microscopic polyangiitis	1	0
Polyarteritis nodosa	1	1
Vasculitis	33	0
Vasculitis necrotising	1	0
Vascular disorders SOC TOTAL	414	5
TOTAL REACTIONS FOR DRUG	26998	215
TOTAL REPORTS	9315	
TOTAL FATAL OUTCOME REPORTS		215