

Case Series Drug Analysis Print

Name: FOI 21/590 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Data Lock Date: 08-Apr-2021 18:30:03
Earliest Reaction Date: 09-Oct-1963
MedDRA Version: MedDRA 23.1

FOI 21/590 Inactivated Drugs Analysis Print. All UK, suspected spontaneous influenza vaccine: reports associated with the inactivated influenza vaccine until Sunday 28th February 2021.

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
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Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	11	0
Anaemia macrocytic	1	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	2	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	23	0
Lymphadenopathy	202	0
Retroperitoneal lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	7	2
Pancytopenia	2	0
Pure white cell aplasia	2	0
Neutropenias		
Agranulocytosis	1	1
Autoimmune neutropenia	2	0
Neutropenia	12	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	2	0
Spleen disorders		
Splenomegaly	1	0
Thrombocytopenias		
Immune thrombocytopenia	29	1
Thrombocytopenia	23	0
Thrombocytopenic purpura	3	0
Thrombotic thrombocytopenic purpura	6	0
Thrombocytoses		
Thrombocytosis	3	0
Blood disorders SOC TOTAL	365	5

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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	4	0
Cardiovascular disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	111	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
Stress cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	2	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	7	3
Angina pectoris	5	0
Myocardial infarction	32	13
Myocardial ischaemia	10	7
<i>Left ventricular failures</i>		
Left ventricular failure	9	2
<i>Mitral valvular disorders</i>		
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiac septal hypertrophy	1	0
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	11	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	13	0
Bradycardia	12	0
Bradycardia foetal	1	0
Cardiac flutter	1	0
Extrasystoles	10	0
Postural orthostatic tachycardia syndrome	2	0
Tachycardia	72	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	3	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0
Atrial fibrillation	30	0
Atrial flutter	2	0
Sinus tachycardia	3	0
Supraventricular tachycardia	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	18	8
Cardio-respiratory arrest	1	1
Ventricular extrasystoles	1	0
Ventricular fibrillation	3	0
Ventricular flutter	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	412	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>Endocrine disorders congenital NEC</i>		
Cystic fibrosis related diabetes	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 face, neck and jaw congenital</i>		
Branchial cyst	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>Ocular disorders congenital NEC</i>		
Colour blindness	1	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	24	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	7	0
Ear discomfort	10	0
Ear disorder	1	0
Ear haemorrhage	1	0
Ear pain	58	0
Ear pruritus	2	0
Ear swelling	7	0
Otorrhoea	2	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>Hearing losses</i>		
Deafness	14	0
Deafness neurosensory	9	0
Deafness transitory	2	0
Deafness unilateral	15	0
Hypoacusis	20	0
Sudden hearing loss	2	0
<i>Hyperacusia</i>		
Hyperacusis	6	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	3	0
Meniere's disease	5	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	2	0
Tinnitus	43	0
Vertigo	89	0
Vertigo positional	4	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	305	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
Thyroiditis subacute	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	3	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>		
Goitre	1	0
Thyroid disorder	1	0
Thyroid mass	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	2	0
Thyrotoxic crisis	1	0
Endocrine disorders SOC TOTAL	17	0

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Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Choroidal effusion	1	0
Vitreous detachment	1	0
Vitreous floaters	6	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
Keratitis	1	0
<i>Corneal structural change, deposit and degeneration</i>		
Keratic precipitates	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	3	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	2	0
Iritis	1	0
Uveitis	3	0
<i>Lacrimation disorders</i>		
Dry eye	6	0
Lacrimal disorder	1	0
Lacrimation increased	18	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Chalazion	1	0
Eyelid irritation	2	0
Eyelid oedema	6	0
Swelling of eyelid	22	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid thickening	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
Orbital haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	5	0
Eye pain	53	0
Eye swelling	67	0
Eyelid disorder	1	0
Eyelid pain	3	0
Ocular discomfort	1	0
Periorbital oedema	11	0
Periorbital swelling	8	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	6	0
Eye inflammation	4	0
Eye irritation	13	0
Eye pruritus	18	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Ocular hyperaemia	25	0
Ocular nerve and muscle disorders		
Eye movement disorder	9	0
Ophthalmoplegia	2	0
Ocular sensation disorders		
Abnormal sensation in eye	1	0
Asthenopia	5	0
Foreign body sensation in eyes	3	0
Photophobia	28	0
Optic disc abnormalities NEC		
Papilloedema	2	0
Optic nerve bleeding and vascular disorders		
Optic ischaemic neuropathy	6	0
Orbital infections, inflammations and irritations		
Orbital myositis	2	0
Pupil disorders		
Mydriasis	2	0
Pupil fixed	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal haemorrhage	1	0
Retinal structural change, deposit and degeneration		
Macular detachment	1	0
Macular hole	1	0
Retinal detachment	1	0
Retinal tear	1	0
Retinal, choroid and vitreous infections and inflammations		
Cystoid macular oedema	1	0
Retinal vasculitis	1	0
Retinopathies NEC		
Acute macular outer retinopathy	1	0
Scleral infections, irritations and inflammations		
Scleritis	3	0
Structural change, deposit and degeneration of eye NEC		
Exophthalmos	1	0
Visual disorders NEC		
Diplopia	15	0
Metamorphopsia	3	0
Photopsia	12	0
Vision blurred	56	0
Visual impairment and blindness (excl colour blindness)		
Blindness	12	0
Blindness transient	8	0
Blindness unilateral	1	0
Visual acuity reduced	4	0
Visual impairment	43	0
Eye disorders SOC TOTAL	538	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>		
Anal erythema	1	0
Anorectal discomfort	2	0
<i>Colitis (excl infective)</i>		
Colitis microscopic	1	0
Colitis ulcerative	2	0
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Teeth brittle	1	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	1	0
Toothache	10	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	407	0
Diarrhoea haemorrhagic	2	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	15	0
Eructation	4	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faeces discoloured	11	0
Faeces hard	1	0
Faeces soft	1	0
Mucous stools	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	18	0
Flatulence	13	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	80	0
Abdominal pain lower	10	0
Abdominal pain upper	122	0
Abdominal rigidity	2	0
Abdominal tenderness	3	0
Gastrointestinal pain	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	14	0
Gastric dilatation	2	0
Gastrooesophageal reflux disease	5	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	3	0
Gastric disorder	1	0
Gastrointestinal disorder	9	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	3	0
Change of bowel habit	3	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	49	0
Anal incontinence	4	0
Dysphagia	47	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	3	0
Frequent bowel movements	4	0
Irritable bowel syndrome	6	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	1	0
Intestinal obstruction	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	5	0
Gingival swelling	1	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	6	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	2	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	5	0
<i>Nausea and vomiting symptoms</i>		
Acetonaemic vomiting	1	0
Nausea	702	0
Retching	8	0
Vomiting	522	0
Vomiting projectile	4	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	3	0
Haematochezia	3	0
Melaena	2	0
<i>Oesophageal ulcers and perforation</i>		
Oesophageal ulcer	1	0
<i>Oral dryness and saliva altered</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Dry mouth	37	0
Lip dry	1	0
Saliva altered	2	0
Salivary hypersecretion	5	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Cheilitis	1	0
Lip blister	3	0
Oral disorder	2	0
Oral lichen planus	2	0
Oral papule	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	3	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	26	0
Lip discolouration	1	0
Lip erythema	4	0
Lip pain	3	0
Odynophagia	2	0
Oral discomfort	6	0
Oral mucosal blistering	7	0
Oral mucosal eruption	2	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	1	0
Oral pain	13	0
Oral pruritus	5	0
Paraesthesia oral	88	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	104	0
Mouth swelling	22	0
Oedema mouth	1	0
Palatal swelling	1	0
Salivary gland disorders NEC		
Salivary gland pain	1	0
Salivary gland enlargements		
Parotid gland enlargement	2	0
Submaxillary gland enlargement	2	0
Salivary gland infections and inflammations		
Salivary duct inflammation	1	0
Stomatitis and ulceration		
Aphthous ulcer	2	0
Mouth ulceration	27	0
Stomatitis	8	0
Tongue disorders		
Glossitis	3	0
Plicated tongue	1	0
Tongue disorder	2	0
Tongue haemorrhage	1	0
Tongue ulceration	3	0
Tongue signs and symptoms		
Glossodynia	4	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Protrusion tongue	1	0
Swollen tongue	75	0
Tongue blistering	2	0
Tongue discolouration	3	0
Tongue discomfort	2	0
Tongue eruption	1	0
Tongue erythema	1	0
Tongue oedema	2	0
Tongue pruritus	1	0
Gastrointestinal disorders SOC TOTAL	2660	1

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site joint discomfort	1	0
Administration site joint movement impairment	2	0
Administration site joint pain	1	0
Administration site nerve damage	1	0
Administration site phlebitis	1	0
Administration site rash	1	0
Administration site swelling	2	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 hypoaesthesia	1	0
Application site inflammation	1	0
Application site pain	5	0
Application site paraesthesia	1	0
Application site pruritus	2	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	3	0
Application site vesicles	2	0
<i>Asthenic conditions</i>		
Asthenia	277	0
Chronic fatigue syndrome	10	0
Fatigue	751	0
Malaise	967	0
Sluggishness	1	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>		
Brain death	1	1
Death	22	22
Sudden cardiac death	1	0
Sudden death	33	33
<i>Febrile disorders</i>		
Hyperpyrexia	4	0
Pyrexia	996	0
<i>Feelings and sensations NEC</i>		
Chills	489	0
Feeling abnormal	111	0
Feeling cold	115	0
Feeling drunk	5	0
Feeling hot	250	0
Feeling jittery	2	0
Feeling of body temperature change	60	0
Hunger	2	0
Sensation of foreign body	9	0
Thirst	11	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Gait disturbances</i>		
Gait disturbance	40	0
Gait inability	13	0
Loss of control of legs	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	55	1
Crepitations	3	0
Crying	10	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
Glassy eyes	1	0
Ill-defined disorder	2	0
Illness	67	0
Induration	20	0
Influenza like illness	558	0
Local reaction	105	0
Moaning	1	0
Multiple organ dysfunction syndrome	8	2
Peripheral swelling	370	0
Screaming	4	0
Secretion discharge	6	0
Swelling	271	0
Swelling face	147	0
Unevaluable event	2	0
<i>Healing abnormal NEC</i>		
Impaired healing	2	0
<i>Hernias NEC</i>		
Hernia	1	0
<i>Inflammations</i>		
Granuloma	25	0
Inflammation	101	0
Soft tissue inflammation	2	0
Systemic inflammatory response syndrome	3	0
<i>Infusion site reactions</i>		
Infusion site pain	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	29	0
Injection site abscess sterile	1	0
Injection site atrophy	2	0
Injection site bruising	24	0
Injection site discharge	1	0
Injection site discolouration	3	0
Injection site discomfort	9	0
Injection site dryness	1	0
Injection site erythema	213	0
Injection site extravasation	2	0
Injection site fibrosis	1	0
Injection site haematoma	1	0
Injection site haemorrhage	9	0

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General disorders General disorders cont'd		
Injection site hypersensitivity	2	0
Injection site hypertrophy	1	0
Injection site hypoaesthesia	5	0
Injection site induration	20	0
Injection site inflammation	83	0
Injection site irritation	4	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	45	0
Injection site movement impairment	8	0
Injection site necrosis	3	0
Injection site oedema	3	0
Injection site pain	263	0
Injection site papule	1	0
Injection site paraesthesia	2	0
Injection site pruritus	88	0
Injection site rash	36	0
Injection site reaction	240	0
Injection site scab	3	0
Injection site scar	3	0
Injection site swelling	128	0
Injection site ulcer	2	0
Injection site urticaria	12	0
Injection site vesicles	10	0
Injection site warmth	65	0
Interactions		
Alcohol interaction	1	0
Drug interaction	42	0
Food interaction	1	0
Inhibitory drug interaction	2	0
Potentiating drug interaction	4	0
Mass conditions NEC		
Mass	19	0
Nodule	1	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	39	0
Chest discomfort	119	0
Chest pain	139	0
Discomfort	37	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Facial pain	17	0
Non-cardiac chest pain	2	0
Pain	617	0
Tenderness	58	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	47	0
Adverse event	4	0
Adverse reaction	3	0
Drug ineffective	11	0
Drug intolerance	1	0
Immediate post-injection reaction	3	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	4	0
Trophic disorders		
Calcinosis	1	0
Hyperplasia	1	0
Ulcers NEC		
Ulcer	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	7	0
Shoulder injury related to vaccine administration	13	0
Vaccination site atrophy	1	0
Vaccination site bruising	57	0
Vaccination site coldness	1	0
Vaccination site cyst	1	0
Vaccination site discharge	1	0
Vaccination site discolouration	9	0
Vaccination site discomfort	21	0
Vaccination site eczema	1	0
Vaccination site erythema	379	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	8	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	67	0
Vaccination site inflammation	72	0
Vaccination site irritation	4	0
Vaccination site joint effusion	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	10	0
Vaccination site joint pain	12	0
Vaccination site joint swelling	1	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	74	0
Vaccination site movement impairment	44	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site pain	467	0
Vaccination site papule	2	0
Vaccination site paraesthesia	7	0
Vaccination site pruritus	92	0
Vaccination site rash	60	0
Vaccination site reaction	31	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 09-Oct-1963

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site scab	1	0
Vaccination site scar	1	0
Vaccination site swelling	381	0
Vaccination site urticaria	5	0
Vaccination site vesicles	7	0
Vaccination site warmth	183	0
General disorders SOC TOTAL	10600	59

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

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	3	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	2	0
Hepatic steatosis	1	0
Hepatitis	10	0
Hepatitis acute	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	60	1

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	235	0
Multiple allergies	1	0
Serum sickness	2	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	3	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	8	0
Drug hypersensitivity	4	0
Food allergy	5	0
Reaction to excipient	9	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	224	1
Anaphylactic shock	26	1
Anaphylactoid reaction	22	0
<i>Atopic disorders</i>		
Seasonal allergy	4	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	5	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	2	0
Decreased immune responsiveness	1	0
Graft versus host disease	1	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	9	0
Immune-mediated adverse reaction	4	0
Sensitisation	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	4	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	594	3

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diarrhoea infectious	1	0
Diverticulitis	2	0
Gastroenteritis	4	0
<i>Atypical mycobacterial infections</i>		
Mycobacterial infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	4	0
Arthritis bacterial	3	0
Bacterial infection	2	0
Cellulitis	87	0
Gangrene	4	1
Injection site cellulitis	13	0
Pneumonia bacterial	1	0
Skin bacterial infection	1	0
Upper respiratory tract infection bacterial	1	0
Vaccination site cellulitis	23	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
Intervertebral discitis	2	0
Vaccination site joint infection	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
<i>Breast infections</i>		
Mastitis	1	0
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	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	29	3
Encephalomyelitis	9	1
Meningitis	5	1
Myelitis	4	0
Panencephalitis	1	0
<i>Clostridia infections</i>		
Gas gangrene	1	1
<i>Coronavirus infections</i>		
COVID-19	3	0
Coronavirus infection	1	0
Suspected COVID-19	2	0
<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	19	0
Otitis media	2	0
<i>Ectoparasitic infestations</i>		

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Acarodermatitis	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	1	0
Eye and eyelid infections		
Conjunctivitis	22	0
Eye infection	1	0
Hordeolum	2	0
Female reproductive tract infections		
Amniotic cavity infection	2	0
Flaviviral infections		
Yellow fever vaccine-associated neurotropic disease	1	0
Fungal infections NEC		
Ear infection fungal	1	0
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		
Genital herpes	1	0
Herpes ophthalmic	1	0
Herpes simplex	7	0
Herpes simplex encephalitis	1	0
Herpes simplex reactivation	1	0
Herpes virus infection	1	0
Herpes zoster	67	0
Herpes zoster meningitis	1	0
Herpes zoster oticus	1	0
Ophthalmic herpes zoster	6	0
Oral herpes	27	0
Varicella	3	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	11	0
Abscess limb	2	0
Device related infection	1	0
Infection	19	0
Injection site abscess	10	0
Injection site infection	11	0
Localised infection	8	0
Lymph gland infection	1	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	9	0
Vaccine breakthrough infection	1	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Infectious transmissions</i>		
Infection via vaccinee	4	0
Nosocomial infection	1	0
Suspected transmission of an infectious agent via product	1	0
Vaccine virus shedding	2	0
<i>Influenza viral infections</i>		
H1N1 influenza	12	0
Influenza	192	1
Pneumonia influenzal	3	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	2	0
Bronchitis	36	0
Infective exacerbation of chronic obstructive airways disease	4	0
Infective pulmonary exacerbation of cystic fibrosis	7	0
Lower respiratory tract infection	127	0
Pneumonia	75	17
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Muscle and soft tissue infections</i>		
Soft tissue infection	3	0
<i>Neisseria infections</i>		
Meningococcal sepsis	1	1
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	3	1
<i>Pseudomonal infections</i>		
Pseudomonas infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Sepsis	23	4
Septic shock	2	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
Pustule	3	0
Rash pustular	2	0
Skin infection	1	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
Staphylococcal infection	2	0
<i>Streptococcal infections</i>		
Pneumonia pneumococcal	1	0
Streptococcal abscess	1	0
Streptococcal infection	3	0
<i>Tinea infections</i>		
Malassezia infection	1	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Tuberculous infections</i>		
Erythema induratum	14	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	1	0
Laryngitis	12	0
Nasopharyngitis	148	0
Pharyngitis	14	0
Rhinitis	24	0
Sinusitis	25	0
Tonsillitis	2	0
Upper respiratory tract infection	31	0
<i>Urinary tract infections</i>		
Cystitis	6	0
Kidney infection	1	0
Pyelonephritis	2	0
Urinary tract infection	14	0
<i>Vascular infections</i>		
Lymphangitis	3	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Encephalitis viral	6	0
Gastroenteritis viral	1	0
Meningitis viral	2	0
Pneumonia viral	1	0
Post viral fatigue syndrome	19	0
Sweating fever	2	0
Vestibular neuronitis	7	0
Viral infection	14	0
Viral labyrinthitis	2	0
Viral myocarditis	1	0
Viral rash	6	0
Viral upper respiratory tract infection	12	0
Infections SOC TOTAL	1379	31

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Cerebral injuries NEC</i>		
Brain herniation	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	27	0
Foetal exposure during pregnancy	16	0
Maternal exposure before pregnancy	1	0
Maternal exposure during pregnancy	24	0
Maternal exposure timing unspecified	2	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
Retinal injury	2	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	17	0
Product use issue	3	0
Vaccination error	1	0
Wrong technique in product usage process	7	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	2	0
Ligament sprain	1	0
Muscle injury	7	0
Muscle rupture	1	0
Muscle strain	3	0
Tendon injury	1	0
Tendon rupture	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	20	0
Nerve root injury thoracic	1	0
<i>Non-site specific injuries NEC</i>		
Eschar	1	0
Fall	27	0
Injury	4	0
Wound	2	0
Wound haemorrhage	1	0
Wound secretion	1	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	1	0
Injection related reaction	1	0
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

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<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
Accidental underdose	1	0
Contraindicated product administered	5	0
Expired product administered	4	0
Extra dose administered	12	0
Inappropriate schedule of product administration	5	0
Incorrect dose administered	6	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	6	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	30	0
Product administered to patient of inappropriate age	32	0
Product administration error	11	0
Product dose omission issue	1	0
Wrong product administered	5	0
<i>Product monitoring errors and issues</i>		
Documented hypersensitivity to administered product	2	0
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	3	0
<i>Skin injuries NEC</i>		
Contusion	72	0
Scar	3	0
Skin abrasion	2	0
Skin laceration	6	0
<i>Thermal burns</i>		
Thermal burn	1	0
<i>Vaccination related complications</i>		
Vaccination complication	4	0
Vaccination failure	27	0
Injuries SOC TOTAL	447	1

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Anti-glomerular basement membrane antibody positive	1	0
Antineutrophil cytoplasmic antibody positive	2	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	11	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose abnormal	1	0
Blood glucose decreased	5	0
Blood glucose fluctuation	3	0
Blood glucose increased	8	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>		
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>Faecal analyses NEC</i>		
White blood cells stool	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	19	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	1	0
Heart rate decreased	14	0
Heart rate increased	70	0
Heart rate irregular	13	0
Pulse abnormal	3	0
<i>Imaging procedures NEC</i>		
Computerised tomogram abnormal	2	0
Optical coherence tomography abnormal	1	0
Positron emission tomogram abnormal	1	0
Ultrasound scan abnormal	2	0
<i>Immune response protein analyses NEC</i>		
Complement factor C3 increased	1	0
<i>Investigations NEC</i>		
Blood test abnormal	2	0
False positive investigation result	1	0
Quality of life decreased	2	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	7	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	5	0
Liver function test abnormal	18	0
Liver function test increased	3	0
<i>Metabolism tests NEC</i>		
Blood ketone body increased	1	0
<i>Microbiology and serology tests NEC</i>		
Blood culture negative	1	0
<i>Mineral and electrolyte analyses</i>		
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	3	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Spinal X-ray abnormal	1	0
<i>Neurologic diagnostic procedures</i>		
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
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	2	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature abnormal	3	0
Body temperature decreased	4	0
Body temperature fluctuation	5	0
Body temperature increased	87	0
Breath sounds abnormal	2	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Grip strength decreased	8	0
Respiratory rate decreased	1	0
Respiratory rate increased	6	0
Weight decreased	13	0
Weight increased	4	0
Platelet analyses		
Platelet count decreased	9	0
Platelet count increased	1	0
Protein analyses NEC		
C-reactive protein	1	0
C-reactive protein abnormal	1	0
C-reactive protein increased	16	0
Globulins increased	1	0
Protein total increased	2	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
Total lung capacity decreased	1	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
Troponin increased	1	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	8	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	4	0
Urinary tract histopathology procedures		

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Biopsy kidney abnormal	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	23	0
Blood pressure diastolic increased	1	0
Blood pressure increased	39	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Cytomegalovirus test positive	1	0
Epstein-Barr virus antibody positive	2	0
Influenza A virus test positive	1	0
Vitamin analyses		
Vitamin D increased	1	0
White blood cell analyses		
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	9	0
Investigations SOC TOTAL	609	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	188	0
Food refusal	2	0
Hypophagia	7	0
Increased appetite	1	0
Salt craving	1	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>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	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	20	0
Feeding disorder	8	0
Food aversion	2	0
Poor feeding infant	1	0
Starvation	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	3	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	12	1
Hypoglycaemia neonatal	2	0
Pseudohypoglycaemia	1	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	3	0
<i>Total fluid volume decreased</i>		
Dehydration	9	0
<i>Total fluid volume increased</i>		

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 09-Oct-1963

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Fluid retention	3	0
Metabolic disorders SOC TOTAL	306	1

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	55	0
Arthritis allergic	1	0
Arthropathy	21	0
Haemarthrosis	2	0
Palindromic rheumatism	1	0
Polyarthritis	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	14	0
Pain in jaw	17	0
Spinal pain	3	0
<i>Bursal disorders</i>		
Bursitis	38	0
<i>Cartilage disorders</i>		
Costochondritis	3	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	2	0
Polymyalgia rheumatica	42	0
Sjogren's syndrome	1	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	47	0
Rotator cuff syndrome	8	0
<i>Joint related signs and symptoms</i>		
Arthralgia	702	0
Joint effusion	6	0
Joint noise	6	0
Joint range of motion decreased	8	0
Joint stiffness	36	0
Joint swelling	78	0
Joint warmth	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	2	0
<i>Muscle infections and inflammations</i>		
Focal myositis	1	0
Myositis	21	0
Myositis-like syndrome	1	0
<i>Muscle pains</i>		
Fibromyalgia	5	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Myalgia	746	0
Muscle related signs and symptoms NEC		
Muscle atrophy	13	0
Muscle discomfort	3	0
Muscle disorder	2	0
Muscle fatigue	11	0
Muscle mass	1	0
Muscle spasms	88	0
Muscle swelling	5	0
Muscle tightness	16	0
Muscle twitching	20	0
Neuropathic muscular atrophy	1	0
Muscle tone abnormalities		
Muscle rigidity	8	0
Torticollis	1	0
Muscle weakness conditions		
Muscular weakness	187	0
Musculoskeletal and connective tissue conditions NEC		
Extremity contracture	1	0
Limb mass	4	0
Mobility decreased	24	0
Muscle contracture	1	0
Musculoskeletal disorder	2	0
Musculoskeletal stiffness	204	0
Posture abnormal	1	0
Weight bearing difficulty	2	0
Winged scapula	4	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	144	0
Flank pain	2	0
Limb discomfort	84	0
Musculoskeletal chest pain	16	0
Musculoskeletal discomfort	20	0
Musculoskeletal pain	11	0
Neck pain	169	0
Pain in extremity	861	0
Rheumatic disorder	3	0
Myopathies		
Diabetic amyotrophy	1	0
Muscle necrosis	1	0
Myopathy	6	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Osteoarthritis	9	0
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	4	0
Rheumatoid arthropathies		
Rheumatoid arthritis	45	0
Soft tissue disorders NEC		

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Axillary mass	5	0
Groin pain	5	0
Neck mass	4	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	2	0
Arthritis reactive	12	0
<i>Synovial disorders</i>		
Synovitis	3	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon disorder	8	0
Tendon pain	3	0
Tendonitis	10	0
Tenosynovitis	2	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	3946	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
<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	2	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	2	0
Skin papilloma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	4	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Urinary tract neoplasms unspecified malignancy NEC</i>		
Renal neoplasm	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	26	3

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	11	0
Hyperreflexia	1	0
Hyporeflexia	3	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	6	0
<i>Acute polyneuropathies</i>		
Acute polyneuropathy	1	0
Guillain-Barre syndrome	189	10
Miller Fisher syndrome	1	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	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
Cerebellar stroke	1	0
Cerebral haemorrhage	6	3
Cerebral infarction	5	2
Cerebrovascular accident	34	5
Ischaemic stroke	3	0
Lacunar infarction	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	3	1
<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	15	0
Balance disorder	69	0
Coordination abnormal	7	0
Dysstasia	18	0
Nystagmus	6	0
<i>Cortical dysfunction NEC</i>		
Aphasia	25	0
Dysgraphia	1	0
Dyspraxia	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	3	0
Vascular dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	14	2
Demyelination	6	0
Neuromyelitis optica spectrum disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	5	0
Consciousness fluctuating	1	0
Depressed level of consciousness	9	0
Lethargy	178	0
Loss of consciousness	110	1
Postictal state	1	0
Sedation	1	0
Somnolence	110	0
Stupor	3	0
Syncope	274	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	20	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	1	0
Hypokinesia	22	0
Motor dysfunction	4	0
Movement disorder	13	0
Up and down phenomenon	1	0
<i>Dystonias</i>		
Dystonia	2	0
<i>Encephalitis NEC</i>		
Bickerstaff's encephalitis	1	0
Encephalitis autoimmune	2	0
Encephalitis post immunisation	1	0
Noninfective encephalitis	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	12	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	64	0
Facial paresis	9	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	30	0
<i>Headaches NEC</i>		
Cluster headache	2	0
Cold-stimulus headache	1	0
Headache	1169	0
Sinus headache	4	0

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Tension headache	13	0
Hydrocephalic conditions		
Hydrocephalus	2	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain oedema	1	0
Intracranial pressure increased	2	1
Intellectual disabilities		
Intellectual disability	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	7	0
Memory loss (excl dementia)		
Amnesia	19	0
Memory impairment	11	0
Transient global amnesia	6	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	7	0
Disturbance in attention	22	0
Mental impairment	5	0
Migraine headaches		
Hemiplegic migraine	1	0
Migraine	64	0
Migraine with aura	8	0
Mononeuropathies		
Carpal tunnel syndrome	2	0
Mononeuropathy multiplex	4	0
Nerve compression	3	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	3	0
Muscle tone abnormal		
Hypertonia	2	0
Hypotonia	8	0
Myelitis (incl infective)		
Myelitis transverse	25	1
Narcolepsy and hypersomnia		
Cataplexy	5	0
Hypersomnia	18	0
Narcolepsy	17	0
Nervous system disorders NEC		
Brain stem syndrome	1	0
Cerebral disorder	2	0
Nervous system disorder	9	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	1	0
Tunnel vision	2	0

Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021
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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Visual field defect	10	0
Neurological signs and symptoms NEC		
Clonus	1	0
Dizziness	738	0
Dizziness exertional	1	0
Dizziness postural	14	0
Drooling	3	0
Head discomfort	21	0
Meningism	11	0
Myoclonus	1	0
Neurological symptom	9	0
Presyncope	34	0
Slow response to stimuli	1	0
Tongue biting	1	0
Unresponsive to stimuli	21	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	2	0
Olfactory nerve disorders		
Anosmia	10	0
Hyposmia	1	0
Parosmia	7	0
Optic nerve disorders NEC		
Optic neuritis	13	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning sensation	76	0
Dysaesthesia	2	0
Formication	5	0
Hyperaesthesia	19	0
Hypoaesthesia	242	0
Paraesthesia	466	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	12	0
Hemiplegia	11	1
Monoparesis	3	0
Monoplegia	13	0
Paralysis	27	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	14	0

Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Neuritis	8	0
Neuropathy peripheral	42	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
Epilepsy	34	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	89	0
Seizure like phenomena	3	0
Status epilepticus	2	0
Tonic clonic movements	1	0
Tonic convulsion	2	0
Sensory abnormalities NEC		
Ageusia	15	0
Allodynia	1	0
Aura	1	0
Dysgeusia	42	0
Hypogeusia	2	0
Loss of proprioception	2	0
Neuralgia	60	0
Post herpetic neuralgia	1	0
Restless legs syndrome	5	0
Sensory disturbance	30	0
Sensory loss	26	0
Taste disorder	17	0
Sleep disturbances NEC		
Poor quality sleep	4	0
Speech and language abnormalities		
Dysarthria	30	0
Incoherent	3	0
Repetitive speech	1	0
Speech disorder	13	0
Spinal cord and nerve root disorders NEC		
Brown-Sequard syndrome	1	0
Myelopathy	4	0
Radiculitis brachial	23	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	8	0
Tremor (excl congenital)		

Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021

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Earliest Reaction Date: 09-Oct-1963

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Essential tremor	1	0
Head titubation	1	0
Tremor	168	0
Trigeminal disorders		
Facial neuralgia	3	0
Trigeminal neuralgia	4	0
Vagus nerve disorders		
Paralysis recurrent laryngeal nerve	1	0
Vocal cord paralysis	1	0
Nervous system disorders SOC TOTAL	5337	31

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	43	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	5	0
Foetal hypokinesia	3	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	2	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	98	11

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device loosening	1	0
<i>Device malfunction events NEC</i>		
Device malfunction	1	0
Oversensing	1	0
<i>Device physical property and chemical issues</i>		
Needle issue	3	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 complaint	1	0
Product quality issue	1	0
<i>Product supply and availability issues</i>		
Product supply issue	1	0
null SOC TOTAL	14	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	5	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	1	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Inappropriate affect	1	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
<i>Anxiety symptoms</i>		
Agitation	19	0
Anxiety	52	0
Nervousness	9	0
Stress	4	0
Tension	2	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
Soliloquy	1	0
<i>Brief psychotic disorder</i>		
Brief psychotic disorder with marked stressors	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
Distractibility	1	0
Mental fatigue	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	96	0
Disorientation	42	0
<i>Decreased physical activity levels</i>		
Catatonia	4	0
<i>Deliria</i>		
Delirium	8	0
<i>Delusional symptoms</i>		
Delusion	2	0
<i>Depressive disorders</i>		
Depression	35	0
Depression suicidal	1	0
<i>Dissociative states</i>		
Dissociation	5	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	79	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>		

Case Series Drug Analysis Print

Name: FOI 21/257 Inactivated influenza vaccine

Report Run Date: 12-Apr-2021
Earliest Reaction Date: 09-Oct-1963

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Anger	3	0
Emotional disorder	3	0
Emotional distress	6	0
Euphoric mood	2	0
Irritability	14	0
Mood altered	5	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	7	0
Phobia	1	0
Phonophobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	5	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	22	0
Hallucination, auditory	1	0
Hallucination, visual	5	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	17	0
Feeling of despair	4	0
Feelings of worthlessness	1	0
Negative thoughts	3	0
Tearfulness	12	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
<i>Mood disorders NEC</i>		
Apathy	4	0
Listless	14	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive disorder	1	0
<i>Panic attacks and disorders</i>		
Panic attack	13	0
Panic disorder	1	0
Panic reaction	5	0
<i>Parasomnias</i>		
Abnormal dreams	7	0
Nightmare	10	0
Rapid eye movements sleep abnormal	1	0
Sleep talking	2	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Deja vu	1	0
Derealisation	2	0
Illusion	1	0
Near death experience	2	0
<i>Pervasive developmental disorders NEC</i>		

Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021
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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	1	0
Psychotic disorder NEC		
Postictal psychosis	1	0
Psychotic disorder	7	0
Sexual desire disorders		
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	28	0
Speech and language usage disturbances		
Disorganised speech	2	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Stereotypies and automatisms		
Automatism	1	0
Bruxism	1	0
Echolalia	1	0
Head banging	1	0
Substance related and addictive disorders		
Alcoholic hangover	1	0
Suicidal and self-injurious behaviour		
Completed suicide	3	3
Intentional self-injury	1	0
Suicidal ideation	5	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	2	0
Intrusive thoughts	1	0
Thinking abnormal	4	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	645	3

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder pain	1	0
Bladder spasm	1	0
Dysuria	8	0
Incontinence	9	0
Micturition urgency	3	0
Pollakiuria	8	0
Urinary incontinence	9	0
Urinary retention	8	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Bladder obstruction	1	0
Urinary bladder haemorrhage	3	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	31	0
Anuria	2	0
Chronic kidney disease	3	0
Oliguria	2	0
Renal failure	8	0
Renal impairment	8	0
Renal injury	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	2	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>Urethral infections and inflammations</i>		
Urethritis noninfective	1	0
<i>Urinary abnormalities</i>		
Chromaturia	6	0
Haematuria	10	1
Ketonuria	2	0
Myoglobinuria	1	0
Proteinuria	2	0
Urine abnormality	3	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<small>Renal & urinary disorders cont'd</small>		
<i>Urinary tract lithiasis (excl renal)</i>		
Ureterolithiasis	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Polyuria	2	0
Renal pain	14	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	173	2

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	8	0
Breast swelling	4	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>		
Dysmenorrhoea	1	0
Menstrual disorder	2	0
Metrorrhagia	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	3	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	2	0
Genital rash	1	0
Pelvic pain	2	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>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	10	0
Vulval ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal burning sensation	2	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	2	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	61	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	3	0
Dyspnoea	347	0
Dyspnoea exertional	4	0
Hyperventilation	9	0
Hypopnoea	7	0
Irregular breathing	2	0
Respiration abnormal	6	0
Respiratory arrest	10	0
Respiratory depression	1	0
Respiratory distress	9	0
Sleep apnoea syndrome	1	0
Tachypnoea	4	0
<i>Bronchial conditions NEC</i>		
Bronchial disorder	1	0
Bronchomalacia	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	116	1
Asthma exercise induced	1	0
Bronchospasm	29	0
Chronic obstructive pulmonary disease	17	3
Obstructive airways disorder	1	0
Status asthmaticus	2	1
Wheezing	104	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	366	0
Haemoptysis	8	0
Productive cough	64	0
Sputum discoloured	3	0
Sputum increased	5	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

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Increased bronchial secretion	2	0
Pleuritic pain	4	0
Pulmonary pain	2	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	58	0
Rhinitis perennial	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	28	0
Nasal oedema	1	0
Nasal polyps	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	11	0
Sinus disorder	12	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	2	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	53	0
Pharyngeal ulceration	1	0
Tonsillar disorder	3	0
Tonsillar hypertrophy	1	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	24	6
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	6	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Respiratory symptom	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Lung disorder	5	0
Respiratory disorder	13	0
Respiratory tract congestion	7	0
Respiratory tract inflammation	2	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>		
Aphonia	21	0
Catarrh	21	0
Choking	6	0
Choking sensation	5	0
Dry throat	14	0
Dysphonia	33	0
Increased viscosity of upper respiratory secretion	1	0
Laryngeal pain	3	0
Nasal discomfort	8	0
Oropharyngeal blistering	3	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	302	0
Paranasal sinus discomfort	1	0
Rhinalgia	1	0
Rhinorrhoea	142	0
Sinus pain	13	0
Sneezing	65	0
Snoring	1	0
Throat irritation	25	0
Throat tightness	57	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	8	0
Yawning	3	0
Respiratory disorders SOC TOTAL	2200	24

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	4	0
<i>Alopecias</i>		
Alopecia	8	0
Alopecia areata	2	0
Madarosis	2	0
<i>Angioedemas</i>		
Angioedema	47	0
Circumoral oedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	80	0
Hyperhidrosis	318	0
Miliaria	5	0
Night sweats	38	0
<i>Bullous conditions</i>		
Blister	55	0
Blister rupture	1	0
Blood blister	8	0
Dermatitis bullous	2	0
Erythema multiforme	31	0
Pemphigoid	9	0
Pemphigus	1	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	0
<i>Connective tissue disorders</i>		
Dermatomyositis	3	0
<i>Dermal and epidermal conditions NEC</i>		
Dermatosis	1	0
Dry skin	22	0
Macule	2	0
Pain of skin	15	0
Papule	12	0
Scab	3	0
Scar pain	1	0
Sensitive skin	4	0
Skin burning sensation	11	0
Skin discolouration	21	0
Skin discomfort	1	0
Skin disorder	7	0
Skin fissures	2	0
Skin induration	11	0
Skin lesion	15	0
Skin necrosis	1	0
Skin reaction	45	0
Skin sensitisation	2	0
Skin swelling	4	0
Skin texture abnormal	5	0
Skin tightness	8	0
Skin warm	119	0
Skin weeping	3	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	20	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermatitis allergic	57	0
Dermatitis contact	1	0
Eczema	30	0
Seborrhoeic dermatitis	5	0
Skin irritation	21	0
Stasis dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	6	0
Drug reaction with eosinophilia and systemic symptoms	2	0
Toxic skin eruption	3	0
<i>Erythemas</i>		
Erythema	545	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>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	7	0
Panniculitis	1	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen planus	5	0
Parapsoriasis	1	0
Pityriasis rosea	8	0
Rash papulosquamous	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	9	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Hair colour changes	1	0
Piloerection	2	0
<i>Pruritus NEC</i>		
Itching scar	1	0
Pruritus	533	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	1	0
Erythrodermic psoriasis	1	0
Guttate psoriasis	3	0
Psoriasis	14	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	19	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Petechiae	13	0
Purpura	35	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	471	0
Rash erythematous	126	0
Rash macular	64	0
Rash maculo-papular	42	0
Rash morbilliform	3	0
Rash papular	43	0
Rash pruritic	96	0
Rash vesicular	12	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	6	0
Subcutaneous emphysema	1	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Pyoderma gangrenosum	1	0
Skin erosion	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	4	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	12	0
Palpable purpura	2	0
Vasculitic rash	14	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	3	0
<i>Urticarias</i>		
Cold urticaria	2	0
Haemorrhagic urticaria	1	0
Idiopathic urticaria	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Mechanical urticaria	1	0
Urticaria	391	0
Urticaria chronic	1	0
Urticaria papular	3	0
Urticarial vasculitis	5	0
Skin disorders SOC TOTAL	3667	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	11	0
Disability	1	0
Hearing disability	1	0
Housebound	1	0
Immobile	3	0
Impaired driving ability	1	0
Impaired work ability	7	0
Loss of personal independence in daily activities	18	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	51	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
Transfusion	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>Renal therapeutic procedures</i>		
Dialysis	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	16	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	4	0
Aortic aneurysm rupture	1	1
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	6	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	3	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	36	2
Neurogenic shock	1	0
Peripheral circulatory failure	1	0
Shock	5	0
Shock symptom	1	0
<i>Haemorrhages NEC</i>		
Haematoma	7	0
Haemorrhage	19	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	6	1
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	21	0
Flushing	76	0
Hot flush	33	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Intermittent claudication	1	0
Ischaemic limb pain	1	0
Peripheral coldness	24	0
Peripheral ischaemia	2	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	1	0
Vasoconstriction	1	0
<i>Phlebitis NEC</i>		
Phlebitis	3	0
<i>Site specific vascular disorders NEC</i>		
Aortic dilatation	1	0
Pallor	89	0
<i>Varicose veins NEC</i>		

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Report Run Date: 12-Apr-2021
 Earliest Reaction Date: 09-Oct-1963

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Varicose vein	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	58	0
<i>Vascular hypotensive disorders</i>		
Hypotension	48	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	1	0
Cryoglobulinaemia	1	0
Granulomatosis with polyangiitis	5	0
Microscopic polyangiitis	1	0
Polyarteritis nodosa	1	1
Vasculitis	36	0
Vasculitis necrotising	1	0
Vascular disorders SOC TOTAL	518	6
TOTAL REACTIONS FOR DRUG	35068	227
TOTAL REPORTS	11760	
TOTAL FATAL OUTCOME REPORTS		227