

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Data Lock Date: 21-Dec-2021 18:30:04
Earliest Reaction Date: 01-Jun-1998
MedDRA Version: MedDRA 24.1

Inactivated Influenza Vaccine Vaccine Analysis Print: Inactivated influenza vaccine analysis print (VAP). All UK, spontaneous suspected ADR reports associated with inactivated influenza vaccine received between 01/08/2020-31/07/2021. Date of data extraction: 21/12/2021.

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Haematological disorders</i>		
Mast cell activation syndrome	2	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	4	0
Lymphadenopathy	45	0
<i>Marrow depression and hypoplastic anaemias</i>		
Pure white cell aplasia	2	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	55	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	20	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	2	0
<i>Mitral valvular disorders</i>		
Mitral valve prolapse	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
Pleuropericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Extrasystoles	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
Cardiac disorders SOC TOTAL	40	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Congenital disorders		
<i>Neurological disorders congenital NEC</i>		
Early onset primary dystonia	1	0
Tourette's disorder	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	2	0
Congenital disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear discomfort	2	0
Ear haemorrhage	1	0
Ear pain	12	0
Ear swelling	2	0
Otorrhoea	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness neurosensory	1	0
Deafness unilateral	1	0
Hypoacusis	3	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	9	0
Vertigo	17	0
Ear disorders SOC TOTAL	54	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid irritation	1	0
Eyelid oedema	1	0
Swelling of eyelid	3	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye pain	6	0
Eye swelling	9	0
Eyelid pain	1	0
Ocular discomfort	1	0
Periorbital swelling	4	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye inflammation	2	0
Eye irritation	3	0
Eye pruritus	3	0
Ocular hyperaemia	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	1	0
Photophobia	2	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular detachment	1	0
Macular hole	1	0
<i>Visual disorders NEC</i>		
Diplopia	2	0
Photopsia	5	0
Vision blurred	12	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	5	0
Blindness transient	2	0
Blindness unilateral	1	0
Visual impairment	10	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	2	0
Eye disorders SOC TOTAL	90	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Dental pain and sensation disorders</i>		
Toothache	3	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	69	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	5	0
Faeces hard	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	2	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	11	0
Abdominal pain lower	1	0
Abdominal pain upper	24	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	15	0
Anal incontinence	1	0
Dysphagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	152	0
Retching	2	0
Vomiting	69	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	2	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	6	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	6	0
Lip erythema	1	0
Lip pain	1	0
Oral pain	4	0
Oral pruritus	2	0
Paraesthesia oral	10	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	13	0
Mouth swelling	6	0
Palatal swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	5	0
<i>Tongue disorders</i>		
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	9	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	442	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site joint movement impairment	2	0
Administration site nerve damage	1	0
Administration site pain	1	0
Administration site swelling	2	0
<i>Application and instillation site reactions</i>		
Application site hypoaesthesia	1	0
Application site joint pain	1	0
Application site pain	3	0
Application site paraesthesia	1	0
Application site pruritus	1	0
Application site rash	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	40	0
Chronic fatigue syndrome	3	0
Fatigue	207	0
Malaise	106	0
Sluggishness	1	0
<i>Febrile disorders</i>		
Pyrexia	130	0
<i>Feelings and sensations NEC</i>		
Chills	103	0
Feeling abnormal	28	0
Feeling cold	27	0
Feeling hot	53	0
Feeling of body temperature change	10	0
Sensation of foreign body	2	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait disturbance	4	0
Gait inability	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	9	0
Illness	12	0
Induration	2	0
Influenza like illness	46	0
Local reaction	1	0
Peripheral swelling	55	0
Swelling	45	0
Swelling face	19	0
<i>Inflammations</i>		
Inflammation	9	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	10	0
Injection site bruising	3	0
Injection site discomfort	1	0
Injection site erythema	18	0
Injection site extravasation	1	0
Injection site hypersensitivity	1	0
Injection site induration	3	0
Injection site inflammation	4	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site irritation	1	0
Injection site mass	5	0
Injection site movement impairment	1	0
Injection site pain	32	0
Injection site paraesthesia	1	0
Injection site pruritus	19	0
Injection site rash	1	0
Injection site reaction	3	0
Injection site swelling	10	0
Injection site urticaria	2	0
Injection site warmth	2	0
Interactions		
Drug interaction	2	0
Mass conditions NEC		
Mass	1	0
Pain and discomfort NEC		
Axillary pain	20	0
Chest discomfort	24	0
Chest pain	16	0
Discomfort	5	0
Facial pain	5	0
Pain	88	0
Tenderness	10	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	13	1
Adverse event	1	0
Drug ineffective	1	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Therapeutic product effect decreased	1	0
Vaccination failure	1	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	4	0
Shoulder injury related to vaccine administration	8	0
Vaccination site bruising	11	0
Vaccination site discolouration	2	0
Vaccination site discomfort	6	0
Vaccination site erythema	78	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	3	0
Vaccination site hypoaesthesia	2	0
Vaccination site induration	15	0
Vaccination site inflammation	11	0
Vaccination site irritation	2	0
Vaccination site joint effusion	1	0
Vaccination site joint movement impairment	7	0
Vaccination site joint pain	6	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	18	0
Vaccination site movement impairment	22	0
Vaccination site pain	128	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site paraesthesia	2	0
Vaccination site pruritus	30	0
Vaccination site rash	16	0
Vaccination site reaction	4	0
Vaccination site swelling	95	0
Vaccination site warmth	53	0
General disorders SOC TOTAL	1768	1

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatic steatosis	1	0
Hepatic disorders SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	39	0
Multiple allergies	1	0
Serum sickness-like reaction	1	0
Type III immune complex mediated reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Allergy to vaccine	6	0
Drug hypersensitivity	3	0
Food allergy	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	33	0
Anaphylactic shock	5	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorder	2	0
Immune-mediated adverse reaction	2	0
Immune system disorders SOC TOTAL	97	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Arthritis bacterial	2	0
Bacterial infection	1	0
Cellulitis	15	0
Upper respiratory tract infection bacterial	1	0
Vaccination site cellulitis	4	0
<i>Bone and joint infections</i>		
Vaccination site joint infection	1	0
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Myelitis	1	0
<i>Coronavirus infections</i>		
COVID-19	6	0
Suspected COVID-19	2	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	6	0
<i>Infections NEC</i>		
Infection	1	0
Injection site infection	1	0
Lymph gland infection	1	0
Vaccination site infection	2	0
<i>Influenza viral infections</i>		
Influenza	21	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Lower respiratory tract infection	8	0
Pneumonia	1	1
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Muscle and soft tissue infections</i>		
Soft tissue infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
Staphylococcal infection	1	0
<i>Tuberculous infections</i>		
Erythema induratum	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	1	0
Nasopharyngitis	10	0
Rhinitis	2	0
Sinusitis	3	0
Tonsillitis	1	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	2	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name		Total	Fatal
Infections	Infections cont'd		
	Viral rash	1	0
Infections SOC TOTAL		107	1

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
 Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during pregnancy	7	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	8	0
Wrong technique in product usage process	3	0
<i>Muscle, tendon and ligament injuries</i>		
Ligament sprain	1	0
Muscle injury	2	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	7	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	1	0
Injection related reaction	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Accidental underdose	1	0
Contraindicated product administered	2	0
Extra dose administered	3	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	1	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	3	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	12	0
Product administered to patient of inappropriate age	4	0
Product administration error	3	0
Wrong product administered	1	0
<i>Product monitoring errors and issues</i>		
Documented hypersensitivity to administered product	2	0
<i>Site specific injuries NEC</i>		
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	4	0
Skin abrasion	1	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Injuries SOC TOTAL	81	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Antineutrophil cytoplasmic antibody positive	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
Blood glucose increased	3	0
<i>ECG investigations</i>		
Electrocardiogram QT prolonged	1	0
<i>Faecal analyses NEC</i>		
White blood cells stool	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	1	0
Heart rate decreased	4	0
Heart rate increased	14	0
Heart rate irregular	3	0
<i>Investigations NEC</i>		
Blood test abnormal	1	0
Laboratory test abnormal	1	0
<i>Liver function analyses</i>		
Liver function test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature increased	9	0
Grip strength decreased	1	0
Respiratory rate increased	1	0
Weight increased	2	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
Protein total increased	1	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	2	0
<i>Reproductive hormone analyses</i>		
Blood testosterone decreased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate decreased	1	0
<i>Urinalysis NEC</i>		
Urine analysis abnormal	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	4	0
Blood pressure increased	7	0
Investigations SOC TOTAL	67	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	43	0
Food refusal	2	0
Increased appetite	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	4	0
Feeding disorder	1	0
<i>Hypoglycaemic conditions NEC</i>		
Pseudohypoglycaemia	1	0
Metabolic disorders SOC TOTAL	53	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	5	0
Arthropathy	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	2	0
Pain in jaw	3	0
Spinal pain	1	0
<i>Bursal disorders</i>		
Bursitis	6	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	1	0
Polymyalgia rheumatica	9	0
Sjogren's syndrome	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	10	0
Rotator cuff syndrome	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	137	0
Joint range of motion decreased	1	0
Joint stiffness	7	0
Joint swelling	16	0
Joint warmth	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Focal myositis	1	0
Myositis	3	0
<i>Muscle pains</i>		
Fibromyalgia	2	0
Myalgia	131	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle discomfort	2	0
Muscle fatigue	7	0
Muscle mass	1	0
Muscle spasms	12	0
Muscle swelling	1	0
Muscle tightness	3	0
Muscle twitching	5	0
<i>Muscle weakness conditions</i>		
Muscular weakness	17	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Extremity contracture	1	0
Limb mass	2	0
Mobility decreased	6	0
Musculoskeletal stiffness	34	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	25	0
Limb discomfort	22	0
Musculoskeletal chest pain	6	0
Musculoskeletal discomfort	6	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Musculoskeletal pain	2	0
Neck pain	28	0
Pain in extremity	182	0
Sacral pain	1	0
<i>Myopathies</i>		
Myopathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Groin pain	3	0
Neck mass	1	0
<i>Tendon disorders</i>		
Tendonitis	5	0
Muscle & tissue disorders SOC TOTAL	721	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm	1	0
<i>Neurofibrosarcomas</i>		
Neurofibrosarcoma	1	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Seborrhoeic keratosis	1	0
Skin papilloma	2	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	9	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	16	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	0
Cerebrovascular accident	3	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	10	0
Coordination abnormal	1	0
Dysstasia	5	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Neuromyelitis optica spectrum disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	1	0
Lethargy	31	0
Loss of consciousness	15	0
Somnolence	20	0
Syncope	31	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	2	0
Hypokinesia	4	0
Movement disorder	2	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	4	0
Facial paralysis	3	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	236	0
Sinus headache	2	0
Tension headache	5	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	2	0
<i>Memory loss (excl dementia)</i>		
Amnesia	3	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	4	0
<i>Migraine headaches</i>		
Migraine	6	0
Migraine with aura	2	0
<i>Mononeuropathies</i>		
Nerve compression	1	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Myelitis (incl infective)</i>		
Myelitis transverse	2	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	5	0
Narcolepsy	1	0
<i>Nervous system disorders NEC</i>		
Cerebral disorder	1	0
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	127	0
Dizziness postural	3	0
Head discomfort	4	0
Presyncope	8	0
Slow response to stimuli	1	0
Unresponsive to stimuli	3	0
<i>Olfactory nerve disorders</i>		
Anosmia	1	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	3	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	22	0
Formication	2	0
Hyperaesthesia	1	0
Hypoaesthesia	41	0
Paraesthesia	60	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Monoplegia	3	0
Paralysis	1	0
Paresis	1	0
<i>Peripheral neuropathies NEC</i>		
Neuralgic amyotrophy	2	0
Neuropathy peripheral	6	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Seizure	7	0
<i>Sensory abnormalities NEC</i>		
Ageusia	3	0
Dysgeusia	7	0
Hypogeusia	1	0
Neuralgia	14	0
Restless legs syndrome	1	0
Sensory disturbance	5	0
Sensory loss	4	0
<i>Speech and language abnormalities</i>		
Dysarthria	2	0
Speech disorder	1	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	5	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	1	0
<i>Tremor (excl congenital)</i>		
Tremor	25	0
Nervous system disorders SOC TOTAL	797	1

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Unintended pregnancies</i>		
Pregnancy with contraceptive device	1	0
Pregnancy conditions SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	7	0
Stress	1	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Soliloquy	1	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	9	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Delusional symptoms</i>		
Delusion	2	0
<i>Depressive disorders</i>		
Depression	3	0
<i>Dissociative states</i>		
Dissociation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	14	0
Middle insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	2	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Emotional distress	1	0
Euphoric mood	2	0
Irritability	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	4	0
Hallucination, auditory	1	0
Hallucination, visual	1	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	2	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
Panic disorder	1	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
Rapid eye movements sleep abnormal	1	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Psychotic disorder NEC</i>		
Psychotic disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	8	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Suicidal ideation	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	88	1

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Dysuria	1	0
Pollakiuria	2	0
Urinary incontinence	1	0
Urinary retention	2	0
<i>Bladder disorders NEC</i>		
Urinary bladder haemorrhage	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Renal failure	1	0
Renal injury	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Urinary abnormalities</i>		
Haematuria	2	0
Urine abnormality	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Polyuria	1	0
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	19	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
Breast swelling	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital discomfort	1	0
Pelvic pain	1	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal disorders NEC</i>		
Vulval ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal burning sensation	1	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	17	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	42	0
Dyspnoea exertional	1	0
Hyperventilation	2	0
Hypopnoea	2	0
Respiration abnormal	2	0
Respiratory arrest	1	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Wheezing	7	0
<i>Coughing and associated symptoms</i>		
Cough	31	0
Haemoptysis	2	0
Productive cough	4	0
Sputum discoloured	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
Nasal polyps	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
Sinus disorder	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal paraesthesia	3	0
Pharyngeal swelling	5	0
Pharyngeal ulceration	1	0
Tonsillar hypertrophy	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	4	2
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	1	0
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	0
Respiratory disorder	1	0
Respiratory tract inflammation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Catarrh	1	0
Dry throat	1	0
Dysphonia	4	0
Nasal discomfort	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	39	0
Rhinorrhoea	13	0
Sinus pain	2	0
Sneezing	8	0
Throat irritation	4	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Throat tightness	3	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	205	2

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Angioedemas</i>		
Angioedema	7	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	11	0
Hyperhidrosis	34	0
Miliaria	1	0
Night sweats	6	0
<i>Bullous conditions</i>		
Blister	3	0
Blood blister	2	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Pain of skin	2	0
Papule	2	0
Scar pain	1	0
Sensitive skin	3	0
Skin discolouration	2	0
Skin disorder	2	0
Skin induration	3	0
Skin lesion	1	0
Skin reaction	10	0
Skin swelling	1	0
Skin warm	22	0
Skin weeping	3	0
<i>Dermatitis and eczema</i>		
Dermatitis	5	0
Dermatitis allergic	11	0
Eczema	3	0
Skin irritation	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
<i>Erythemas</i>		
Erythema	86	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Pityriasis rosea	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	101	0
<i>Psoriatic conditions</i>		
Psoriasis	3	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Petechiae	1	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Nodular rash	1	0
Rash	55	0
Rash erythematous	15	0
Rash macular	5	0
Rash maculo-papular	1	0
Rash papular	7	0
Rash pruritic	13	0
Rash vesicular	3	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	1	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Skin vasculitides</i>		
Hypersensitivity vasculitis	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Cold urticaria	1	0
Haemorrhagic urticaria	1	0
Urticaria	54	0
Skin disorders SOC TOTAL	505	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	2	0
Immobile	3	0
Impaired work ability	3	0
Loss of personal independence in daily activities	6	0
<i>Social issues NEC</i>		
Impaired quality of life	1	0
Social circumstances SOC TOTAL	15	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 01-Jun-1998

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
Surgical & medical procedures SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: Inactivated Influenza Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 01-Jun-1998

Data Lock Date: 21-Dec-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	2	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	2	1
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	4	0
Hot flush	4	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	6	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	9	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	4	0
<i>Vascular hypotensive disorders</i>		
Hypotension	6	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Granulomatosis with polyangiitis	1	0
Vasculitis	3	0
Vascular disorders SOC TOTAL	49	1
TOTAL REACTIONS FOR DRUG	5296	7
TOTAL REPORTS	1632	
TOTAL FATAL OUTCOME REPORTS		7