Report Run Date: 22-Dec-2021

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

Earliest Reaction Date: 15-Jul-2015 MedDRA Version: MedDRA 24.1

Live Influenza Vaccine Live influenza vaccine analysis print (VAP). All UK, Vaccine Analysis Print: spontaneous suspected ADR reports associated with live influenza vaccine received between 01/08/2020-

31/07/2021. Date of data extraction: 21/12/2021.

Name: Live Influenza Vaccine Vaccine Analysis Print

Date: 22-Dec-2021
Data Lock Date: 21-Dec-2021 18:30:04
Action Date: 15-Jul-2015
MedDRA Version: MedDRA 24.1 Report Run Date: 22-Dec-2021 Earliest Reaction Date: 15-Jul-2015

Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenopathy	1	0
Thrombocytopenias		
Immune thrombocytopenia	1	0
Blood disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Congenital disorders		
Neurological disorders congenital NEC		
Tourette's disorder	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	1	0
Ear pain	1	0
Ear swelling	1	0
Ear disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Eye disorders		
Lacrimation disorders		
Lacrimation increased	7	0
Lid, lash and lacrimal infections, irritations and inflammations		
Erythema of eyelid	1	0
Swelling of eyelid	1	0
Ocular disorders NEC		
Eye pain	1	0
Eye swelling	2	0
Ocular discomfort	1	0
Periorbital swelling	1	0
Ocular infections, inflammations and associated manifestations		
Ocular hyperaemia	3	0
Ocular nerve and muscle disorders		
Eye movement disorder	1	0
Ophthalmoplegia	1	0
Ocular sensation disorders		
Photophobia	1	0
Visual disorders NEC		
Diplopia	1	0
Vision blurred	1	0
Eve disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Colitis (excl infective)		
Colitis	1	0
Diarrhoea (excl infective)		
Diarrhoea	8	0
Faecal abnormalities NEC		
Abnormal faeces	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	4	0
Abdominal pain lower	2	0
Abdominal pain upper	6	0
Gastrointestinal disorders NEC		
Appendix disorder	1	0
Gastrointestinal disorder	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1	0
Gingival disorders, signs and symptoms NEC		
Gingival pain	1	0
Gingival swelling	1	0
Nausea and vomiting symptoms		
Nausea	7	0
Retching	1	0
Vomiting	20	0
Vomiting projectile	1	0
Non-site specific gastrointestinal haemorrhages		
Haematochezia	1	0
Oral soft tissue swelling and oedema		
Mouth swelling	1	0
Tongue disorders		
Tongue geographic	1	0
Tongue signs and symptoms		
Strawberry tongue	1	0
Gastrointestinal disorders SOC TOTAL	60	l o

Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site rash	1	0
Asthenic conditions		
Asthenia	3	0
Fatigue	11	0
Malaise	7	0
Death and sudden death		
Death	2	2
Febrile disorders		
Pyrexia	51	0
Feelings and sensations NEC		
Chills	5	0
Feeling abnormal	2	0
Feeling cold	1	0
Feeling hot	1	0
Gait disturbances		
Gait disturbance	1	0
General signs and symptoms NEC		
Crying	1	0
Illness	5	0
Induration	1	0
Influenza like illness	6	0
Peripheral swelling	1	0
Swelling face	5	0
Oedema NEC		
Face oedema	1	0
Pain and discomfort NEC		
Chest discomfort	1	0
Pain	6	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
No reaction on previous exposure to drug	1	0
Vaccination site reactions		
Vaccination site pain	1	0
General disorders SOC TOTAL	115	2

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	4	0
Allergies to foods, food additives, drugs and other chemicals		
Food allergy	2	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	4	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
Immune system disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Appendicitis	1	0
Bacterial infections NEC		
Bacterial infection	1	0
Ear infections		
Ear infection	1	0
Labyrinthitis	1	0
Otitis media chronic	1	0
Infectious transmissions		
Infection via vaccinee	1	0
Influenza viral infections		
Influenza	5	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	1	0
Upper respiratory tract infections		
Nasopharyngitis	4	0
Upper respiratory tract infection	3	0
Viral infections NEC		
Metapneumovirus infection	1	0
Infections SOC TOTAL	20	0

Reaction Name	Total	Fatal
Injuries		
Accidental exposures to product		
Accidental exposure to product	2	0
Exposures to agents or circumstances NEC		
Exposure to vaccinated person	1	0
Non-site specific injuries NEC		
Fall	1	0
Off label uses		
Off label use	1	0
Product administration errors and issues		
Accidental overdose	1	0
Contraindicated product administered	1	0
Expired product administered	1	0
Product administered to patient of inappropriate age	2	0
Product administration error	1	0
Skin injuries NEC		
Contusion	2	0
Injuries SOC TOTAL	13	0

Reaction Name	Total	Fatal
Investigations		
Blood gas and acid base analyses		
Oxygen saturation decreased	1	0
Neurologic diagnostic procedures		
Sensory level abnormal	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature increased	6	0
Platelet analyses		
Platelet count decreased	1	0
Investigations SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	17	'l ol
Metabolic disorders SOC TOTAL	17	'l o

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related signs and symptoms		
Arthralgia	3	0
Joint swelling	1	0
Muscle infections and inflammations		
Myositis	1	0
Muscle pains		
Myalgia	5	0
Muscle weakness conditions		
Muscular weakness	1	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	1	0
Musculoskeletal and connective tissue pain and discomfort		
Neck pain	2	0
Pain in extremity	3	0
Muscle & tissue disorders SOC TOTAL	17	0

Reaction Name	Total	Fatal
Neoplasms		
Bone sarcomas		
Ewing's sarcoma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	<u>Fatal</u>
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	2	0
Coordination and balance disturbances		
Balance disorder	1	0
Disturbances in consciousness NEC		
Lethargy	11	0
Loss of consciousness		0
Somnolence	1	
Syncope	5	0
Facial cranial nerve disorders		
Bell's palsy	1	
Facial paresis	1	0
Headaches NEC		
Headache	31	0
Increased intracranial pressure disorders		
Brain oedema	1	0
Muscle tone abnormal		
Hypotonia	2	0
Narcolepsy and hypersomnia		
Cataplexy	3	
Narcolepsy	3	0
Neurological signs and symptoms NEC		
Dizziness	3	0
Head discomfort	1	_
Unresponsive to stimuli		0
Paraesthesias and dysaesthesias		
Paraesthesia	2	0
Paralysis and paresis (excl cranial nerve)		
Paralysis		0
Seizures and seizure disorders NEC		
Epilepsy		
Seizure	1	0
Sensory abnormalities NEC		
Sensory disturbance	1	0
Tremor (excl congenital)		
Head titubation	1	0
Nervous system disorders SOC TOTAL	75	<u> </u>

Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	2	0
Emotional and mood disturbances NEC		
Irritability	1	0
Hallucinations (excl sleep-related)		
Hallucination	2	0
Mental disorders NEC		
Mental disorder	1	. 0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive disorder	1	. 0
Parasomnias		
Somnambulism	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	1	0
Sleep disorders NEC		
Sleep disorder	1	0
Tic disorders		
Tic	3	0
Psychiatric disorders SOC TOTAL	13	0

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Apnoea	2	0
Dyspnoea	4	0
Respiratory distress	2	0
Tachypnoea	1	0
Bronchospasm and obstruction		
Asthma	3	0
Bronchospasm	1	0
Wheezing	5	0
Conditions associated with abnormal gas exchange		
Hypoxia	1	0
Coughing and associated symptoms		
Cough	8	0
Productive cough	1	0
Laryngeal spasm, oedema and obstruction		
Stridor	1	0
Nasal congestion and inflammations		
Nasal congestion	19	0
Nasal disorders NEC		
Epistaxis	18	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinus congestion	3	0
Respiratory tract disorders NEC		
Respiratory disorder	1	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
Upper respiratory tract signs and symptoms		
Dry throat	1	0
Dysphonia	2	0
Nasal discomfort	2 5	0
Oropharyngeal pain	12	0
Rhinorrhoea	34	0
Sneezing	10	0
Throat clearing	1	0
Throat irritation	1	0
Throat tightness	1	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	140	

Reaction Name	Total	Fatal
Skin disorders		
Apocrine and eccrine gland disorders		
Cold sweat	2	0
Hyperhidrosis	1	0
Bullous conditions		
Blister	1	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Pain of skin	1	0
Papule	1	0
Skin discolouration	1	0
Skin lesion	1	0
Skin reaction	2	0
Skin warm	3	0
Dermatitis and eczema		
Dermatitis allergic	2	0
Dermatitis contact	2	0
Eczema	1	0
Erythemas		
Erythema	3	0
Exfoliative conditions		
Skin exfoliation	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Pruritus NEC		
Pruritus	7	0
Psoriatic conditions		
Psoriasis	1	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Petechiae	1	0
Rashes, eruptions and exanthems NEC		
Rash	13	0
Rash erythematous	3	0
Rash macular	4	0
Rash pruritic	5	0
Urticarias		
Urticaria	13	0
Skin disorders SOC TOTAL	71	0

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Reaction Name	Total	Fatal
Social circumstances		
Social issues NEC		
Contraindication to vaccination	1	0
Social circumstances SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Peripheral circulatory failure	1	0
Shock	1	0
Peripheral vascular disorders NEC		
Cyanosis	2	0
Flushing	1	0
Site specific vascular disorders NEC		
Pallor	5	0
Vascular disorders SOC TOTAL	10	0
TOTAL REACTIONS FOR DRUG	604	2
TOTAL REPORTS	212	
TOTAL FATAL OUTCOME REPORTS		2