

## Case Series Drug Analysis Print

**Name: FOI 21/877- Live Attenuated Influenza Virus Vaccine DAP  
2019**

Report Run Date: 09-Aug-2021

Data Lock Date: 08-Aug-2021 18:30:04

Earliest Reaction Date: 15-Oct-2015

MedDRA Version: MedDRA 24.0

FOI 21/877- Influenza All spontaneous suspected UK Adverse Drug Reaction  
Live Virus Vaccine (ADR) reports associated with the Live Attenuated Influenza  
DAP 2019: Virus Vaccine in 2019

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	5	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	9	0
Ear swelling	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Lacrimation increased	5	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Lid, lash and lacrimal structural disorders</i>		
Lagophthalmos	1	0
<i>Ocular disorders NEC</i>		
Eye pain	2	0
Eye swelling	4	0
Periorbital swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye pruritus	2	0
Ocular hyperaemia	5	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	3	0
<b>Eye disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	25	0
<i>Flatulence, bloating and distension</i>		
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	19	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	16	0
Retching	1	0
Vomiting	58	0
Vomiting projectile	4	0
<i>Oral dryness and saliva altered</i>		
Lip dry	2	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	2	0
<i>Oral soft tissue signs and symptoms</i>		
Lip pain	2	0
Oral mucosal blistering	1	0
Oral pain	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	4	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>146</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	9	0
Chronic fatigue syndrome	1	0
Fatigue	24	0
Malaise	27	0
<i><b>Febrile disorders</b></i>		
Pyrexia	153	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	10	0
Feeling abnormal	2	0
Feeling cold	2	0
Feeling hot	1	0
Hunger	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	2	0
Crying	1	0
Illness	23	0
Induration	1	0
Influenza like illness	24	0
Peripheral swelling	2	0
Swelling	1	0
Swelling face	6	0
<i><b>Inflammations</b></i>		
Inflammation	1	0
<i><b>Pain and discomfort NEC</b></i>		
Chest pain	4	0
Pain	24	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Vaccination failure	1	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site pain	1	0
<b>General disorders SOC TOTAL</b>	<b>321</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Gastroenteritis	1	0
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	3	0
<i><b>Bordetella infections</b></i>		
Pertussis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Myelitis	1	0
<i><b>Ear infections</b></i>		
Ear infection	3	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	3	0
<i><b>Herpes viral infections</b></i>		
Varicella	1	0
<i><b>Infections NEC</b></i>		
Localised infection	1	0
Purulence	1	0
Respiratory tract infection	1	0
<i><b>Infectious transmissions</b></i>		
Infection via vaccinee	53	0
Vaccine virus shedding	9	0
<i><b>Influenza viral infections</b></i>		
H1N1 influenza	1	0
Influenza	26	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Lower respiratory tract infection	7	0
<i><b>Skin structures and soft tissue infections</b></i>		
Impetigo	1	0
<i><b>Staphylococcal infections</b></i>		
Furuncle	1	0
<i><b>Streptococcal infections</b></i>		
Scarlet fever	3	0
Streptococcal infection	1	0
<i><b>Upper respiratory tract infections</b></i>		
Croup infectious	5	0
Nasopharyngitis	15	0
Rhinitis	1	0
Sinusitis	2	0
Tonsillitis	7	0
<i><b>Viral infections NEC</b></i>		
Viral infection	1	0
Viral myositis	1	0
<b>Infections SOC TOTAL</b>	<b>151</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
Accidental exposure to product by child	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Product use in unapproved indication	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	2	0
<i>Off label uses</i>		
Off label use	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature fluctuation	1	0
Body temperature increased	3	0
<b>Investigations SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	36	0
Increased appetite	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Joint related signs and symptoms</i>		
Arthralgia	6	0
<i>Muscle pains</i>		
Myalgia	13	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	3	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Neck pain	2	0
Pain in extremity	10	0
<i>Synovial disorders</i>		
Synovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	1	0
<i><b>Coordination and balance disturbances</b></i>		
Balance disorder	1	0
<i><b>Disturbances in consciousness NEC</b></i>		
Lethargy	22	0
Loss of consciousness	2	0
Somnolence	5	0
Syncope	10	0
<i><b>Facial cranial nerve disorders</b></i>		
Bell's palsy	1	0
<i><b>Headaches NEC</b></i>		
Headache	70	0
<i><b>Mixed cranial nerve disorders</b></i>		
Palatal palsy	1	0
<i><b>Muscle tone abnormal</b></i>		
Hypotonia	2	0
<i><b>Narcolepsy and hypersomnia</b></i>		
Cataplexy	3	0
Hypersomnia	2	0
Narcolepsy	5	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	17	0
Presyncope	1	0
Unresponsive to stimuli	2	0
<i><b>Paraesthesias and dysaesthesias</b></i>		
Hyperaesthesia	1	0
<i><b>Seizures and seizure disorders NEC</b></i>		
Epilepsy	1	0
Partial seizures	1	0
Seizure	3	0
<i><b>Sensory abnormalities NEC</b></i>		
Neuralgia	1	0
<i><b>Tremor (excl congenital)</b></i>		
Tremor	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>155</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Agitation	1	0
Anxiety	2	0
<i><b>Behaviour and socialisation disturbances</b></i>		
Aggression	1	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	2	0
Disorientation	1	0
<i><b>Deliria</b></i>		
Delirium	1	0
Delirium febrile	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	2	0
<i><b>Dyssomnias</b></i>		
Poor quality sleep	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Irritability	2	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	3	0
Hallucination, auditory	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Depressed mood	1	0
<i><b>Mood disorders NEC</b></i>		
Listless	3	0
<i><b>Narcolepsy and associated conditions</b></i>		
Hypnagogic hallucination	1	0
<i><b>Obsessive-compulsive disorders and symptoms</b></i>		
Obsessive-compulsive disorder	1	0
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	1	0
<i><b>Panic attacks and disorders</b></i>		
Panic reaction	1	0
<i><b>Parasomnias</b></i>		
Nightmare	2	0
Sleep talking	1	0
Sleep terror	3	0
Somnambulism	1	0
<i><b>Tic disorders</b></i>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>34</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	11	0
<i>Bronchospasm and obstruction</i>		
Asthma	9	0
Wheezing	15	0
<i>Coughing and associated symptoms</i>		
Cough	91	0
Productive cough	6	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	17	0
Nasal inflammation	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	28	0
Nasal mucosal ulcer	1	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Tonsillar hypertrophy	1	0
Velopharyngeal incompetence	1	0
<i>Respiratory signs and symptoms NEC</i>		
Respiratory symptom	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Nasal discomfort	3	0
Oropharyngeal pain	44	0
Paranasal sinus discomfort	1	0
Rhinalgia	3	0
Rhinorrhoea	51	0
Sinus pain	2	0
Sneezing	9	0
Throat irritation	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>300</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Dermatitis acneiform	1	0
<b><i>Angioedemas</i></b>		
Angioedema	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	5	0
Hyperhidrosis	4	0
Night sweats	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Papule	1	0
Skin reaction	1	0
Skin warm	1	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis allergic	1	0
Eczema	1	0
Skin irritation	2	0
<b><i>Erythemas</i></b>		
Erythema	10	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	8	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		
Purpura	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	25	0
Rash erythematous	2	0
Rash macular	4	0
Rash papular	4	0
Rash pruritic	4	0
<b><i>Urticarias</i></b>		
Urticaria	16	0
<b>Skin disorders SOC TOTAL</b>	<b>95</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	7	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>1359</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>399</b>	