

Case Series Drug Analysis Print

Name: FOI 21.645 - chicken pox vaccine DAP

Report Run Date: 27-Jun-2021

Data Lock Date: 25-Jun-2021 18:30:03

Earliest Reaction Date: 09-Dec-1999

MedDRA Version: MedDRA 24.0

FOI 21.645 - chicken pox vaccine DAP: All UK spontaneous suspected adverse drug reaction reports associated with the chicken pox vaccine up to and including 25/06/2021

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	4	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
Blood disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Tachycardia	1	0
Cardiac disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Aplasia cutis congenita	1	0
Congenital disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	2	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness neurosensory	1	0
Deafness unilateral	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
Ear disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Dry eye	1	0
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	4	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
Eye swelling	3	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Optic disc abnormalities NEC</i>		
Optic discs blurred	1	0
<i>Visual disorders NEC</i>		
Vision blurred	2	0
Eye disorders SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	11	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intussusception	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	12	0
Retching	2	0
Vomiting	20	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	3	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	63	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	4	0
Fatigue	9	0
Malaise	20	0
<i>Febrile disorders</i>		
Pyrexia	47	0
<i>Feelings and sensations NEC</i>		
Chills	2	0
Feeling abnormal	1	0
Feeling cold	2	0
Feeling drunk	1	0
Feeling hot	5	0
Feeling of body temperature change	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
<i>General signs and symptoms NEC</i>		
Crying	2	0
Disease progression	1	0
Illness	3	0
Influenza like illness	6	0
Local reaction	2	0
Peripheral swelling	6	0
Swelling	4	0
Swelling face	1	0
<i>Injection site reactions</i>		
Injection site erythema	8	0
Injection site inflammation	4	0
Injection site mass	1	0
Injection site pain	4	0
Injection site papule	1	0
Injection site pruritus	2	0
Injection site rash	2	0
Injection site reaction	6	0
Injection site swelling	5	0
Injection site urticaria	2	0
Injection site vesicles	1	0
<i>Oedema NEC</i>		
Localised oedema	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Discomfort	4	0
Pain	8	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	6	0
Therapeutic response decreased	1	0
Therapy non-responder	5	0
Vaccination failure	32	0
<i>Vaccination site reactions</i>		
Vaccination site discolouration	1	0
Vaccination site erythema	4	0
Vaccination site irritation	1	0
Vaccination site pain	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site papule	1	0
Vaccination site pruritus	1	0
Vaccination site rash	2	0
Vaccination site reaction	1	0
Vaccination site swelling	1	0
Vaccination site vesicles	1	0
General disorders SOC TOTAL	229	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	5	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
Anaphylactoid reaction	1	0
Immune system disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Skin bacterial infection	3	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
<i>Fungal infections NEC</i>		
Genital infection fungal	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	1	0
Herpes zoster	3	0
Varicella	60	0
Varicella post vaccine	3	0
Varicella zoster virus infection	2	0
<i>Infections NEC</i>		
Abscess limb	1	0
Infection	1	0
<i>Infectious transmissions</i>		
Infection via vaccinee	2	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	2	0
Pneumonia	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Skin infection	1	0
<i>Streptococcal infections</i>		
Beta haemolytic streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	2	0
Nasopharyngitis	1	0
<i>Viral infections NEC</i>		
Bronchiolitis	1	0
Conjunctivitis viral	1	0
Post viral fatigue syndrome	1	0
Infections SOC TOTAL	95	0

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Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure before pregnancy	1	0
Maternal exposure timing unspecified	1	0
<i>Off label uses</i>		
Off label use	3	0
<i>Product administration errors and issues</i>		
Contraindicated product administered	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Scar	1	0
Skin abrasion	2	0
Skin laceration	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
<i>Vaccination related complications</i>		
Post vaccination syndrome	1	0
Vaccination complication	1	0
Injuries SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Investigations		
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	2	0
Heart rate irregular	1	0
Pulse abnormal	1	0
<i>Immunology analyses NEC</i>		
Antibody test negative	2	0
<i>Liver function analyses</i>		
Liver function test abnormal	1	0
<i>Microbiology and serology tests NEC</i>		
Seroconversion test negative	1	0
Serology negative	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
Body temperature increased	5	0
Respiratory rate increased	1	0
Weight decreased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
<i>Virus identification and serology</i>		
Varicella virus test negative	1	0
Investigations SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	3	0
Hypophagia	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
Metabolic disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthropathy	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2	0
Joint swelling	2	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	3	0
<i>Muscle pains</i>		
Myalgia	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Pain in extremity	4	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
Muscle & tissue disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	1	0
Neoplasms SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Coordination abnormal	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	5	0
Loss of consciousness	1	0
Postictal state	1	0
Somnolence	6	0
Syncope	5	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	3	0
Psychomotor hyperactivity	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
<i>Eye movement disorders</i>		
VIth nerve paralysis	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
Facial paralysis	2	0
<i>Headaches NEC</i>		
Headache	17	0
<i>Increased intracranial pressure disorders</i>		
Intracranial pressure increased	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	3	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	7	0
Presyncope	2	0
Slow response to stimuli	1	0
Unresponsive to stimuli	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	2	0
Hypoaesthesia	4	0
Paraesthesia	8	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	1	0
<i>Seizures and seizure disorders NEC</i>		

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Nervous system disorders		
Epilepsy	1	0
Febrile convulsion	1	0
Seizure	2	0
Sensory abnormalities NEC		
Neuralgia	2	0
Sensory disturbance	1	0
Speech and language abnormalities		
Dysarthria	3	0
Language disorder	1	0
Speech disorder	1	0
Tremor (excl congenital)		
Tremor	7	0
Trigeminal disorders		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	108	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature rupture of membranes	1	0
Pregnancy conditions SOC TOTAL	5	0

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product complaint	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
Staring	2	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	1	0
<i>Behaviour and socialisation disturbances</i>		
Social avoidant behaviour	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	3	0
Disorientation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	2	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychiatric symptoms	1	0
<i>Mood alterations with depressive symptoms</i>		
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Orgasmic disorders and disturbances</i>		
Orgasm abnormal	1	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Perception disturbances NEC</i>		
Illusion	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	2	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	1	0
Urinary retention	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	5	0
Grunting	1	0
Hypopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
<i>Coughing and associated symptoms</i>		
Cough	5	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	5	0
Rhinorrhoea	2	0
Throat tightness	1	0
Yawning	3	0
Respiratory disorders SOC TOTAL	25	0

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Skin disorders		
<i>Acnes</i>		
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	2	0
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	1	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	8	0
Erythema multiforme	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Papule	4	0
Scab	2	0
Skin disorder	1	0
Skin induration	1	0
Skin lesion	4	0
Skin plaque	1	0
Skin reaction	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	1	0
Eczema	4	0
<i>Dermatitis ascribed to specific agent</i>		
Fixed eruption	1	0
<i>Erythemas</i>		
Erythema	8	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Skin exfoliation	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	18	0
<i>Psoriatic conditions</i>		
Psoriasis	2	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	44	0
Rash erythematous	4	0
Rash macular	3	0
Rash maculo-papular	4	0
Rash morbilliform	1	0
Rash papular	7	0
Rash pruritic	5	0
Rash vesicular	30	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Urticarias</i>		
Urticaria	5	0
Skin disorders SOC TOTAL	180	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	6	0
Vascular disorders SOC TOTAL	8	0
TOTAL REACTIONS FOR DRUG	862	0
TOTAL REPORTS	315	