

## Case Series Drug Analysis Print

**Name: FOI 21.645 - Shingles vaccine DAP**

Report Run Date: 27-Jun-2021

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

Earliest Reaction Date: 09-Feb-2006

MedDRA Version: MedDRA 24.0

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

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	1	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	1	0
<b><i>Leukocytoses NEC</i></b>		
Neutrophilia	1	0
<b><i>Leukopenias NEC</i></b>		
Lymphopenia	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymph node pain	2	0
Lymphadenopathy	9	0
<b><i>Neutropenias</i></b>		
Neutropenia	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	1	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>18</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	13	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	1	0
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	1
Myocardial infarction	2	2
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Tachycardia	3	0
<i>Right ventricular failures</i>		
Right ventricular failure	1	1
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	6	0
<b>Cardiac disorders SOC TOTAL</b>	<b>34</b>	<b>5</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	9	0
<i>Hearing disorders NEC</i>		
Dysacusis	1	0
<i>Hearing losses</i>		
Deafness	3	0
Deafness neurosensory	3	0
Deafness unilateral	6	0
Hypoacusis	4	0
Sudden hearing loss	1	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	9	0
Vertigo	12	0
Vertigo positional	2	0
<b>Ear disorders SOC TOTAL</b>	<b>51</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Thyroid pain	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous floaters	3	0
<i><b>Corneal structural change, deposit and degeneration</b></i>		
Corneal lesion	1	0
Keratopathy	1	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	1	0
Eyelid ptosis	1	0
<i><b>Glaucomas (excl congenital)</b></i>		
Glaucoma	2	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iridocyclitis	2	0
Uveitis	4	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	1	0
Lacrimation increased	2	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Eyelid irritation	1	0
Swelling of eyelid	3	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Dacryostenosis acquired	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	2	0
Eye pain	10	0
Eye swelling	3	0
Eyelid disorder	1	0
Lens disorder	1	0
Periorbital oedema	2	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye discharge	3	0
Eye inflammation	2	0
Eye irritation	3	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	1	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	5	0
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Macular degeneration	1	0
Macular detachment	1	0
Macular hole	1	0
<i><b>Retinal, choroid and vitreous infections and inflammations</b></i>		
Cystoid macular oedema	1	0
Necrotising retinitis	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	3	0
Halo vision	1	0
Photopsia	2	0
Vision blurred	6	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Blindness	1	0
Blindness transient	1	0
Blindness unilateral	2	0
Visual acuity reduced	3	0
Visual impairment	6	0
<b>Eye disorders SOC TOTAL</b>	<b>89</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i><b>Anal and rectal signs and symptoms</b></i>		
Anal pruritus	1	0
<i><b>Dental pain and sensation disorders</b></i>		
Toothache	2	0
<i><b>Diarrhoea (excl infective)</b></i>		
Diarrhoea	25	0
<i><b>Dyspeptic signs and symptoms</b></i>		
Dyspepsia	5	0
Eructation	1	0
<i><b>Faecal abnormalities NEC</b></i>		
Faeces discoloured	1	0
<i><b>Flatulence, bloating and distension</b></i>		
Abdominal distension	1	0
Flatulence	2	0
<i><b>Gastrointestinal and abdominal pains (excl oral and throat)</b></i>		
Abdominal pain	14	0
Abdominal pain lower	1	0
Abdominal pain upper	4	0
<i><b>Gastrointestinal atonic and hypomotility disorders NEC</b></i>		
Constipation	4	0
Gastrooesophageal reflux disease	1	0
<i><b>Gastrointestinal disorders NEC</b></i>		
Functional gastrointestinal disorder	3	0
<i><b>Gastrointestinal dyskinetic disorders</b></i>		
Change of bowel habit	1	0
Defaecation disorder	1	0
<i><b>Gastrointestinal signs and symptoms NEC</b></i>		
Abdominal discomfort	10	0
Anal incontinence	1	0
Dysphagia	4	0
<i><b>Gastrointestinal stenosis and obstruction NEC</b></i>		
Intestinal obstruction	1	0
<i><b>Gingival disorders, signs and symptoms NEC</b></i>		
Gingival discomfort	1	0
Gingival pain	2	0
Gingival swelling	1	0
Gingival ulceration	1	0
<i><b>Nausea and vomiting symptoms</b></i>		
Nausea	59	0
Retching	1	0
Vomiting	30	0
<i><b>Non-site specific gastrointestinal haemorrhages</b></i>		
Melaena	1	0
<i><b>Oral dryness and saliva altered</b></i>		
Dry mouth	3	0
Lip dry	1	0
<i><b>Oral soft tissue disorders NEC</b></i>		
Chapped lips	1	0
Lip blister	2	0
Oral disorder	2	0
Oral lichen planus	1	0
<i><b>Oral soft tissue haemorrhages</b></i>		
Oral blood blister	1	0



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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Oral soft tissue signs and symptoms</i></b>		
Lip pain	1	0
Oral mucosal blistering	4	0
Oral pain	2	0
Paraesthesia oral	3	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	9	0
Mouth swelling	2	0
<b><i>Salivary gland disorders NEC</i></b>		
Salivary gland pain	1	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	1	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	6	0
Stomatitis	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	4	0
Swollen tongue	3	0
Tongue blistering	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>228</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	27	0
Fatigue	50	0
Malaise	85	0
<i>Death and sudden death</i>		
Death	3	3
Sudden death	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	47	0
<i>Feelings and sensations NEC</i>		
Chills	24	0
Feeling abnormal	9	0
Feeling cold	8	0
Feeling hot	18	0
Feeling of body temperature change	5	0
Sensation of foreign body	2	0
<i>Gait disturbances</i>		
Gait disturbance	4	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	14	0
Disease prodromal stage	1	0
Exercise tolerance decreased	1	0
General physical health deterioration	2	0
Ill-defined disorder	1	0
Illness	2	0
Induration	3	0
Influenza like illness	28	0
Local reaction	16	0
Multiple organ dysfunction syndrome	3	0
Peripheral swelling	38	0
Swelling	26	0
Swelling face	4	0
<i>Inflammations</i>		
Inflammation	9	0
<i>Injection site reactions</i>		
Injection site bruising	5	0
Injection site discolouration	1	0
Injection site discomfort	1	0
Injection site dryness	1	0
Injection site eczema	2	0
Injection site erythema	42	0
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	1	0
Injection site induration	2	0
Injection site inflammation	2	0
Injection site injury	1	0
Injection site irritation	1	0
Injection site mass	1	0
Injection site pain	21	0

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<b>General disorders</b> General disorders cont'd		
Injection site paraesthesia	3	0
Injection site pruritus	18	0
Injection site rash	9	0
Injection site reaction	5	0
Injection site scab	1	0
Injection site swelling	30	0
Injection site urticaria	1	0
Injection site vesicles	6	0
Injection site warmth	10	0
<b>Interactions</b>		
Drug interaction	1	0
<b>Oedema NEC</b>		
Localised oedema	1	0
Oedema	1	0
Oedema peripheral	2	0
<b>Pain and discomfort NEC</b>		
Axillary pain	3	0
Chest discomfort	5	0
Chest pain	15	0
Discomfort	4	0
Facial pain	11	0
Non-cardiac chest pain	1	0
Pain	112	0
Tenderness	7	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	1	0
Drug ineffective	4	0
Therapeutic response unexpected	2	0
Therapy non-responder	1	0
Vaccination failure	18	0
<b>Vaccination site reactions</b>		
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	4	0
Vaccination site discomfort	2	0
Vaccination site dryness	1	0
Vaccination site erythema	27	0
Vaccination site hypersensitivity	1	0
Vaccination site induration	4	0
Vaccination site inflammation	6	0
Vaccination site irritation	1	0
Vaccination site joint pain	2	0
Vaccination site joint swelling	1	0
Vaccination site mass	4	0
Vaccination site movement impairment	1	0
Vaccination site necrosis	2	0
Vaccination site nodule	1	0
Vaccination site pain	27	0
Vaccination site pallor	1	0
Vaccination site papule	3	0
Vaccination site pruritus	7	0
Vaccination site rash	12	0
Vaccination site reaction	5	0
Vaccination site scar	1	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site swelling	26	0
Vaccination site ulcer	1	0
Vaccination site urticaria	2	0
Vaccination site vesicles	3	0
Vaccination site warmth	13	0
<b>General disorders SOC TOTAL</b>	<b>947</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	11	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Haemophagocytic lymphohistiocytosis	1	0
Immunisation reaction	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>22</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Diverticulitis	1	0
<b><i>Adenoviral infections</i></b>		
Adenoviral conjunctivitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Cellulitis	10	0
Conjunctivitis bacterial	1	0
Folliculitis	2	0
Injection site cellulitis	2	0
Keratitis bacterial	1	0
Vaccination site cellulitis	2	0
<b><i>Bone and joint infections</i></b>		
Intervertebral discitis	1	0
<b><i>Candida infections</i></b>		
Oral candidiasis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	4	0
<b><i>Dental and oral soft tissue infections</i></b>		
Gingivitis	1	0
<b><i>Ear infections</i></b>		
Labyrinthitis	3	0
Otitis media	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	2	0
Eye infection	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	2	0
<b><i>Herpes viral infections</i></b>		
Disseminated varicella zoster vaccine virus infection	2	1
Disseminated varicella zoster virus infection	2	1
Eczema herpeticum	1	0
Genital herpes simplex	2	0
Genital herpes zoster	1	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes zoster	300	0
Herpes zoster cutaneous disseminated	5	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster necrotising retinopathy	2	0
Herpes zoster oticus	4	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	12	0
Oral herpes	7	0
Varicella	34	0
Varicella post vaccine	1	0
Varicella zoster virus infection	7	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	1	0
Infection reactivation	1	0
Vaccine breakthrough infection	1	0

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<b>Infections</b> Infections cont'd		
<i><b>Infectious transmissions</b></i>		
Infection via vaccinee	4	0
Secondary transmission	8	0
<i><b>Influenza viral infections</b></i>		
Influenza	2	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	3	0
<i><b>Mycoplasma infections</b></i>		
Mycoplasma infection	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Blister infected	2	0
Dermatitis infected	2	0
Impetigo	1	0
Injection site pustule	1	0
Pustule	5	0
Rash pustular	2	0
Skin infection	1	0
<i><b>Streptococcal infections</b></i>		
Pneumonia pneumococcal	1	0
<i><b>Upper respiratory tract infections</b></i>		
Laryngitis	1	0
Nasopharyngitis	3	0
Sinusitis	1	0
Upper respiratory tract infection	1	0
<i><b>Urinary tract infections</b></i>		
Cystitis	1	0
Urinary tract infection	2	0
<i><b>Viral infections NEC</b></i>		
Encephalitis viral	1	0
Pleurisy viral	1	0
Sweating fever	1	0
Vestibular neuronitis	1	0
Viral infection	2	0
<b>Infections SOC TOTAL</b>	<b>475</b>	<b>2</b>



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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	3	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	9	0
Product use in unapproved indication	1	0
Product use issue	2	0
Vaccination error	5	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	2	0
Nerve root injury	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Eschar	1	0
Fall	3	0
Wound secretion	1	0
<b><i>Occupational exposures</i></b>		
Occupational exposure to product	2	0
<b><i>Overdoses NEC</i></b>		
Overdose	1	0
<b><i>Product administration errors and issues</i></b>		
Contraindicated product administered	5	0
Extra dose administered	1	0
Inappropriate schedule of product administration	1	0
Incorrect route of product administration	8	0
Product administered at inappropriate site	2	0
Product administered to patient of inappropriate age	2	0
Product administration error	1	0
Wrong product administered	3	0
<b><i>Product monitoring errors and issues</i></b>		
Labelled drug-disease interaction medication error	1	0
<b><i>Product prescribing errors and issues</i></b>		
Product prescribing error	1	0
<b><i>Product storage errors and issues in the product use system</i></b>		
Product storage error	2	0
<b><i>Skin injuries NEC</i></b>		
Contusion	5	0
Skin abrasion	2	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>67</b>	<b>0</b>

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<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose increased	2	0
<i><b>Cell marker analyses</b></i>		
Prostatic specific antigen increased	1	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
International normalised ratio increased	1	0
<i><b>ECG investigations</b></i>		
Electrocardiogram QT prolonged	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate increased	4	0
Heart rate irregular	2	0
<i><b>Liver function analyses</b></i>		
Liver function test abnormal	3	0
<i><b>Ophthalmic function diagnostic procedures</b></i>		
Intraocular pressure increased	2	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	9	0
Neurological examination abnormal	1	0
Weight decreased	1	0
<i><b>Pituitary analyses anterior</b></i>		
Blood thyroid stimulating hormone decreased	1	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	1	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	5	0
<i><b>Renal function analyses</b></i>		
Blood creatinine increased	1	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output increased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure increased	4	0
<i><b>White blood cell analyses</b></i>		
Neutrophil count decreased	1	0
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>47</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21.645 - Shingles vaccine DAP

Report Run Date: 27-Jun-2021

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

Earliest Reaction Date: 09-Feb-2006

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	21	0
Hypophagia	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Type 2 diabetes mellitus	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	1	0
Food intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	4	0
Feeding disorder	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>33</b>	<b>0</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	3	0
Arthropathy	1	0
Polyarthritis	2	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	1	0
Pain in jaw	4	0
<b><i>Bursal disorders</i></b>		
Bursitis	2	0
<b><i>Connective tissue disorders NEC</i></b>		
Polymyalgia rheumatica	19	0
Scleroderma	1	0
<b><i>Extremity deformities</i></b>		
Hand deformity	1	0
<b><i>Joint related disorders NEC</i></b>		
Periarthritis	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	90	0
Joint stiffness	4	0
Joint swelling	12	0
<b><i>Lupus erythematosus (incl subtypes)</i></b>		
Systemic lupus erythematosus	1	0
<b><i>Muscle infections and inflammations</i></b>		
Polymyositis	1	0
<b><i>Muscle pains</i></b>		
Myalgia	65	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle fatigue	1	0
Muscle spasms	4	0
Muscle tightness	1	0
Muscle twitching	1	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	1	0
Torticollis	2	0
Trismus	1	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	16	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Mobility decreased	2	0
Musculoskeletal stiffness	14	0
Weight bearing difficulty	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	27	0
Limb discomfort	3	0
Musculoskeletal chest pain	7	0
Musculoskeletal discomfort	5	0
Musculoskeletal pain	1	0
Neck pain	15	0
Pain in extremity	98	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	2	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	4	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Soft tissue disorders NEC</i></b>		
Groin pain	7	0
<b><i>Spine and neck deformities</i></b>		
Spinal stenosis	1	0
<b><i>Spondyloarthropathies</i></b>		
Arthritis reactive	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>424</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021

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

Earliest Reaction Date: 09-Feb-2006

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>B-cell small lymphocytic lymphomas</i>		
B-cell small lymphocytic lymphoma	1	0
<i>Lymphomas unspecified NEC</i>		
Central nervous system lymphoma	1	1
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Myelofibrosis	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	1	0
<i>Skin neoplasms benign</i>		
Leser-Trelat sign	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>7</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: FOI 21.645 - Shingles vaccine DAP

Report Run Date: 27-Jun-2021  
Earliest Reaction Date: 09-Feb-2006

Data Lock Date: 25-Jun-2021 18:30:03  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	2	0
<i><b>Acute polyneuropathies</b></i>		
Acute polyneuropathy	1	0
Guillain-Barre syndrome	4	0
Miller Fisher syndrome	1	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Cerebral infarction	1	0
Cerebrovascular accident	4	0
<i><b>Chronic polyneuropathies</b></i>		
Demyelinating polyneuropathy	1	0
<i><b>Coma states</b></i>		
Coma	1	0
<i><b>Coordination and balance disturbances</b></i>		
Ataxia	3	0
Balance disorder	12	0
Coordination abnormal	1	0
Nystagmus	1	0
<i><b>Cortical dysfunction NEC</b></i>		
Aphasia	1	0
<i><b>Demyelinating disorders NEC</b></i>		
Acute disseminated encephalomyelitis	1	1
<i><b>Disturbances in consciousness NEC</b></i>		
Consciousness fluctuating	1	0
Depressed level of consciousness	2	0
Lethargy	23	0
Loss of consciousness	3	0
Somnolence	8	0
Syncope	11	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Fine motor skill dysfunction	1	0
Movement disorder	2	0
<i><b>Eye movement disorders</b></i>		
Microvascular cranial nerve palsy	1	0
<i><b>Facial cranial nerve disorders</b></i>		
Bell's palsy	14	0
Facial paralysis	7	0
Facial paresis	1	0
<i><b>Generalised tonic-clonic seizures</b></i>		
Generalised tonic-clonic seizure	1	0
<i><b>Headaches NEC</b></i>		
Cluster headache	2	0
Headache	124	0
Occipital neuralgia	1	0
Tension headache	1	0
<i><b>Increased intracranial pressure disorders</b></i>		
Brain oedema	1	0
<i><b>Lumbar spinal cord and nerve root disorders</b></i>		
Sciatica	3	0
<i><b>Memory loss (excl dementia)</b></i>		
Amnesia	4	0
Memory impairment	3	0
Transient global amnesia	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	1	0
Disturbance in attention	3	0
Mental impairment	1	0
<b><i>Migraine headaches</i></b>		
Migraine	3	0
<b><i>Mononeuropathies</i></b>		
Sciatic nerve neuropathy	1	0
<b><i>Motor neurone diseases</i></b>		
Motor neurone disease	1	1
<b><i>Multiple sclerosis acute and progressive</i></b>		
Multiple sclerosis	2	0
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	1	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	3	0
<b><i>Nervous system disorders NEC</i></b>		
Central nervous system lesion	1	0
Nervous system disorder	1	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	47	0
Dizziness postural	1	0
Head discomfort	1	0
Meningism	1	0
Presyncope	1	0
Unresponsive to stimuli	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	16	0
Formication	4	0
Hyperaesthesia	10	0
Hypoaesthesia	18	0
Paraesthesia	48	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Hemiparesis	1	0
<b><i>Partial complex seizures</i></b>		
Dreamy state	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuralgic amyotrophy	3	0
Neuritis	1	0
Neuropathy peripheral	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Seizure	6	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	1	0
Allodynia	2	0
Dysgeusia	5	0
Electric shock sensation	4	0
Neuralgia	45	0
Post herpetic neuralgia	21	0
Sensory disturbance	4	0
Sensory loss	2	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	5	0



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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Incoherent	1	0
Speech disorder	3	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculitis brachial	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	9	0
<b><i>Trigeminal disorders</i></b>		
Facial neuralgia	1	0
Trigeminal neuralgia	4	0
<b>Nervous system disorders SOC TOTAL</b>	<b>537</b>	<b>2</b>

# Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021

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

Earliest Reaction Date: 09-Feb-2006

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Prolonged labour	1	0
Prolonged pregnancy	1	0
<i>Maternal complications of labour NEC</i>		
Labour complication	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>4</b>	<b>0</b>

## Case Series Drug Analysis Print

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Earliest Reaction Date: 09-Feb-2006

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	1	0
Staring	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	4	0
Anxiety	3	0
Nervousness	2	0
Stress	2	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Paranoia	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	12	0
Disorientation	5	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Deliria</i></b>		
Delirium	1	0
<b><i>Depressive disorders</i></b>		
Depression	4	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	6	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	1	0
Emotional disorder	1	0
Irritability	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	2	0
Hallucination, visual	2	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Decreased interest	1	0
Depressed mood	2	0
Feeling of despair	1	0
Tearfulness	1	0
<b><i>Mood disorders NEC</i></b>		
Listless	2	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	1	0
<b><i>Parasomnias</i></b>		
Rapid eye movements sleep abnormal	1	0
<b><i>Perception disturbances NEC</i></b>		
Illusion	1	0
<b><i>Psychiatric symptoms NEC</i></b>		
Psychiatric symptom	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	4	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	1	0
<b><i>Thinking disturbances</i></b>		
Impaired reasoning	1	0

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Earliest Reaction Date: 09-Feb-2006

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Reaction Name	Total	Fatal
Psychiatric disorders <sup>P</sup> Psychiatric disorders cont'd		
<b>Psychiatric disorders SOC TOTAL</b>	<b>69</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021

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

Earliest Reaction Date: 09-Feb-2006

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Dysuria	1	0
Incontinence	1	0
Micturition disorder	1	0
Micturition urgency	1	0
Pollakiuria	5	0
Urinary incontinence	3	0
Urinary retention	1	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	1	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Urinary tract disorder	1	0
<i><b>Renal disorders NEC</b></i>		
Single functional kidney	1	0
<i><b>Renal failure and impairment</b></i>		
Renal failure	2	0
Renal impairment	2	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	2	0
Haematuria	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Costovertebral angle tenderness	1	0
Renal pain	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>26</b>	<b>0</b>

## Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile erythema	1	0
Penile pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	1	0
Genital rash	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal discomfort	1	0
Vulvovaginal pruritus	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	14	0
Respiration abnormal	1	0
Tachypnoea	1	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchiectasis	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	2	0
Chronic obstructive pulmonary disease	1	0
Wheezing	2	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	11	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Alveolitis	1	0
Pneumonitis	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	3	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinonasal obstruction	1	0
Sinus congestion	2	0
Sinus disorder	1	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Interstitial lung disease	1	0
Lung consolidation	1	0
Organising pneumonia	1	0
Pulmonary alveolar haemorrhage	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal oedema	2	0
Pharyngeal swelling	2	0
Tonsillar ulcer	1	0
<i><b>Pleural conditions NEC</b></i>		
Pleural adhesion	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	1	0
<i><b>Pulmonary hypertensions</b></i>		
Pulmonary hypertension	1	0
<i><b>Pulmonary oedemas</b></i>		
Acute lung injury	1	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	2	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory disorder	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Catarrh	1	0
Dry throat	2	0
Dysphonia	2	0

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Earliest Reaction Date: 09-Feb-2006

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Increased upper airway secretion	1	0
Oropharyngeal pain	11	0
Rhinorrhoea	5	0
Sinus pain	1	0
Sneezing	1	0
Throat irritation	1	0
Throat tightness	4	0
Upper-airway cough syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>93</b>	<b>0</b>



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

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	3	0
<b><i>Alopecias</i></b>		
Alopecia	1	0
Alopecia totalis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	4	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	2	0
Hyperhidrosis	11	0
Miliaria	1	0
Night sweats	3	0
<b><i>Bullous conditions</i></b>		
Blister	60	0
Dermatitis bullous	3	0
Erythema multiforme	1	0
Pemphigoid	1	0
Stevens-Johnson syndrome	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	8	0
Macule	2	0
Pain of skin	13	0
Papule	17	0
Scab	10	0
Sensitive skin	6	0
Skin burning sensation	4	0
Skin discolouration	3	0
Skin discomfort	3	0
Skin lesion	12	0
Skin reaction	8	0
Skin sensitisation	5	0
Skin texture abnormal	1	0
Skin warm	11	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	5	0
Dermatitis allergic	11	0
Eczema	6	0
Skin irritation	12	0
Stasis dermatitis	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	1	0
<b><i>Erythemas</i></b>		
Erythema	79	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	6	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Granuloma annulare	1	0
<b><i>Hyperkeratoses</i></b>		
Hyperkeratosis	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	2	0

## Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Pityriasis rubra pilaris	1	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	1	0
Solar dermatitis	1	0
<b>Pruritus NEC</b>		
Pruritus	122	0
<b>Psoriatic conditions</b>		
Psoriasis	3	0
Pustular psoriasis	1	0
<b>Purpura and related conditions</b>		
Petechiae	2	0
Purpura	6	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	140	0
Rash erythematous	33	0
Rash macular	10	0
Rash maculo-papular	12	0
Rash morbilliform	1	0
Rash papular	18	0
Rash pruritic	44	0
Rash vesicular	135	0
<b>Rosaceas</b>		
Rosacea	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Skin mass	1	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin ulcer	1	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	3	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	1	0
<b>Skin vasculitides</b>		
Hypersensitivity vasculitis	4	0
Vasculitic rash	4	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	2	0
<b>Urticarias</b>		
Urticaria	36	0
<b>Skin disorders SOC TOTAL</b>	<b>905</b>	<b>0</b>

# Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021

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

Earliest Reaction Date: 09-Feb-2006

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	2	0
Loss of personal independence in daily activities	2	0
<i>Social issues NEC</i>		
Contraindication to vaccination	10	0
<b>Social circumstances SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Report Run Date: 27-Jun-2021

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

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MedDRA Version: MedDRA 24.0

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	3	0
<i>Renal therapeutic procedures</i>		
Renal transplant	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>4</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 21.645 - Shingles vaccine DAP

Report Run Date: 27-Jun-2021

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

Earliest Reaction Date: 09-Feb-2006

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	3	0
Shock	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	4	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	5	0
<i>Varicose veins NEC</i>		
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>26</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>4135</b>	<b>14</b>
<b>TOTAL REPORTS</b>	<b>1436</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>14</b>