

Case Series Drug Analysis Print

Name: Shingles vaccine analysis print

Report Run Date: 15-May-2023

Data Lock Date: 12-May-2023 16:30:03

Earliest Reaction Date: 14-Jan-2005

MedDRA Version: MedDRA 26.0

Shingles vaccine analysis print: All UK spont received for shingles vaccines up to and including 12th May 2023

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| Reaction Name | Total | Fatal |
|---------------------------------------|-----------|----------|
| Blood disorders | | |
| Anaemias NEC | | |
| Anaemia | 1 | 0 |
| Anaemias haemolytic immune | | |
| Autoimmune haemolytic anaemia | 1 | 0 |
| Leukocytoses NEC | | |
| Lymphocytosis | 1 | 0 |
| Neutrophilia | 1 | 0 |
| Leukopenias NEC | | |
| Lymphopenia | 1 | 0 |
| Lymphatic system disorders NEC | | |
| Lymph node pain | 2 | 0 |
| Lymphadenopathy | 17 | 0 |
| Neutropenias | | |
| Neutropenia | 1 | 0 |
| Spleen disorders | | |
| Splenomegaly | 1 | 0 |
| Thrombocytopenias | | |
| Immune thrombocytopenia | 1 | 0 |
| Thrombocytopenia | 2 | 0 |
| Blood disorders SOC TOTAL | 29 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Cardiac disorders | | |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Palpitations | 18 | 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 | 3 | 2 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 2 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Arrhythmia | 2 | 0 |
| Bradycardia | 1 | 0 |
| Tachycardia | 4 | 0 |
| <i>Right ventricular failures</i> | | |
| Right ventricular failure | 1 | 1 |
| <i>Supraventricular arrhythmias</i> | | |
| Atrial fibrillation | 6 | 0 |
| Cardiac disorders SOC TOTAL | 43 | 5 |

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|--|----------|----------|
| Congenital disorders | | |
| <i>Skin and subcutaneous tissue disorders congenital NEC</i> | | |
| Aplasia cutis congenita | 1 | 0 |
| Congenital disorders SOC TOTAL | 1 | 0 |

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| Reaction Name | Total | Fatal |
|-------------------------------------|-----------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear pain | 14 | 0 |
| Ear swelling | 1 | 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 | 5 | 0 |
| Sudden hearing loss | 2 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Meniere's disease | 1 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Tinnitus | 10 | 0 |
| Vertigo | 17 | 0 |
| Vertigo positional | 2 | 0 |
| Ear disorders SOC TOTAL | 65 | 0 |

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|--------------------------------------|----------|----------|
| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Thyroiditis | 1 | 0 |
| <i>Thyroid disorders NEC</i> | | |
| Goitre | 1 | 0 |
| Thyroid pain | 1 | 0 |
| Endocrine disorders SOC TOTAL | 3 | 0 |

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|--|-------|-------|
| Eye disorders | | |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Vitreous floaters | 4 | 0 |
| <i>Corneal structural change, deposit and degeneration</i> | | |
| Corneal lesion | 1 | 0 |
| Corneal thickening | 1 | 0 |
| Keratopathy | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 1 | 0 |
| Eyelid ptosis | 1 | 0 |
| <i>Glaucomas (excl congenital)</i> | | |
| Glaucoma | 2 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Iridocyclitis | 2 | 0 |
| Uveitis | 4 | 0 |
| <i>Lacrimation disorders</i> | | |
| Dry eye | 1 | 0 |
| Lacrimation increased | 4 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Eyelid irritation | 1 | 0 |
| Eyelid rash | 1 | 0 |
| Swelling of eyelid | 5 | 0 |
| <i>Lid, lash and lacrimal structural disorders</i> | | |
| Dacryostenosis acquired | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye disorder | 4 | 0 |
| Eye pain | 13 | 0 |
| Eye swelling | 6 | 0 |
| Eyelid disorder | 1 | 0 |
| Eyelids pruritus | 1 | 0 |
| Lens disorder | 1 | 0 |
| Periorbital oedema | 2 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye discharge | 4 | 0 |
| Eye inflammation | 3 | 0 |
| Eye irritation | 3 | 0 |
| Eye pruritus | 1 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 1 | 0 |
| Ocular myasthenia | 1 | 0 |
| Ophthalmoplegia | 2 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Asthenopia | 1 | 0 |
| Photophobia | 7 | 0 |
| <i>Pupil disorders</i> | | |
| Mydriasis | 1 | 0 |
| <i>Retinal structural change, deposit and degeneration</i> | | |
| Macular degeneration | 1 | 0 |
| Macular detachment | 1 | 0 |
| Macular hole | 1 | 0 |
| <i>Retinal, choroid and vitreous infections and inflammations</i> | | |
| Cystoid macular oedema | 1 | 0 |
| Necrotising retinitis | 1 | 0 |
| <i>Visual disorders NEC</i> | | |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Eye disorders Eye disorders cont'd | | |
| Diplopia | 4 | 0 |
| Halo vision | 1 | 0 |
| Photopsia | 2 | 0 |
| Vision blurred | 8 | 0 |
| Visual impairment and blindness (excl colour blindness) | | |
| Blindness | 2 | 0 |
| Blindness transient | 2 | 0 |
| Blindness unilateral | 2 | 0 |
| Visual acuity reduced | 3 | 0 |
| Visual impairment | 10 | 0 |
| Eye disorders SOC TOTAL | 121 | 0 |

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|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Anal and rectal signs and symptoms</i> | | |
| Anal pruritus | 1 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Crohn's disease | 1 | 0 |
| <i>Dental disorders NEC</i> | | |
| Tooth disorder | 1 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Toothache | 2 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 47 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 6 | 0 |
| Eructation | 1 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Faeces discoloured | 1 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 1 | 0 |
| Flatulence | 3 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 20 | 0 |
| Abdominal pain lower | 1 | 0 |
| Abdominal pain upper | 15 | 0 |
| Gastrointestinal pain | 2 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 5 | 0 |
| Duodenogastric reflux | 1 | 0 |
| Gastrooesophageal reflux disease | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Functional gastrointestinal disorder | 3 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Change of bowel habit | 1 | 0 |
| Defaecation disorder | 1 | 0 |
| Dyschezia | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 14 | 0 |
| Anal incontinence | 1 | 0 |
| Dysphagia | 4 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intestinal obstruction | 1 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival discomfort | 1 | 0 |
| Gingival pain | 3 | 0 |
| Gingival swelling | 1 | 0 |
| Gingival ulceration | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 93 | 0 |
| Retching | 3 | 0 |
| Vomiting | 63 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Melaena | 1 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Dry mouth | 4 | 0 |
| Lip dry | 1 | 0 |

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|--|------------|----------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| <i>Oral soft tissue disorders NEC</i> | | |
| Chapped lips | 1 | 0 |
| Lip blister | 3 | 0 |
| Oral disorder | 2 | 0 |
| Oral lichen planus | 1 | 0 |
| <i>Oral soft tissue haemorrhages</i> | | |
| Oral blood blister | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Lip pain | 2 | 0 |
| Oral mucosal blistering | 4 | 0 |
| Oral pain | 3 | 0 |
| Paraesthesia oral | 3 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 13 | 0 |
| Mouth swelling | 2 | 0 |
| <i>Rectal inflammations NEC</i> | | |
| Proctitis | 2 | 0 |
| <i>Salivary gland disorders NEC</i> | | |
| Salivary gland pain | 1 | 0 |
| <i>Salivary gland enlargements</i> | | |
| Parotid gland enlargement | 1 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Lip ulceration | 1 | 0 |
| Mouth ulceration | 7 | 0 |
| Stomatitis | 2 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Glossodynia | 4 | 0 |
| Swollen tongue | 6 | 0 |
| Tongue blistering | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 366 | 0 |

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|--|-------|-------|
| General disorders | | |
| Administration site reactions NEC | | |
| Administration site swelling | 1 | 0 |
| Application and instillation site reactions | | |
| Application site erythema | 1 | 0 |
| Asthenic conditions | | |
| Asthenia | 37 | 0 |
| Chronic fatigue syndrome | 1 | 0 |
| Fatigue | 96 | 0 |
| Malaise | 138 | 0 |
| Complications associated with device NEC | | |
| Injury associated with device | 3 | 0 |
| Death and sudden death | | |
| Death | 3 | 3 |
| Sudden death | 1 | 1 |
| Febrile disorders | | |
| Hyperpyrexia | 1 | 0 |
| Pyrexia | 126 | 0 |
| Feelings and sensations NEC | | |
| Chills | 48 | 0 |
| Feeling abnormal | 16 | 0 |
| Feeling cold | 15 | 0 |
| Feeling drunk | 1 | 0 |
| Feeling hot | 25 | 0 |
| Feeling of body temperature change | 9 | 0 |
| Sensation of foreign body | 2 | 0 |
| Gait disturbances | | |
| Gait disturbance | 6 | 0 |
| Gait inability | 2 | 0 |
| General signs and symptoms NEC | | |
| Condition aggravated | 14 | 0 |
| Crying | 2 | 0 |
| Disease prodromal stage | 1 | 0 |
| Disease progression | 1 | 0 |
| Exercise tolerance decreased | 1 | 0 |
| General physical health deterioration | 2 | 0 |
| Ill-defined disorder | 1 | 0 |
| Illness | 15 | 0 |
| Induration | 3 | 0 |
| Influenza like illness | 35 | 0 |
| Local reaction | 17 | 0 |
| Multiple organ dysfunction syndrome | 2 | 0 |
| Peripheral swelling | 57 | 0 |
| Swelling | 33 | 0 |
| Swelling face | 10 | 0 |
| Inflammations | | |
| Inflammation | 14 | 0 |
| Injection site reactions | | |
| Injected limb mobility decreased | 1 | 0 |
| 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 |

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|---|-------|-------|
| General disorders General disorders cont'd | | |
| Injection site erythema | 53 | 0 |
| Injection site hypersensitivity | 2 | 0 |
| Injection site hypoaesthesia | 1 | 0 |
| Injection site induration | 2 | 0 |
| Injection site inflammation | 4 | 0 |
| Injection site injury | 1 | 0 |
| Injection site irritation | 1 | 0 |
| Injection site joint pain | 1 | 0 |
| Injection site mass | 2 | 0 |
| Injection site pain | 33 | 0 |
| Injection site papule | 1 | 0 |
| Injection site paraesthesia | 3 | 0 |
| Injection site pruritus | 20 | 0 |
| Injection site rash | 13 | 0 |
| Injection site reaction | 6 | 0 |
| Injection site scab | 1 | 0 |
| Injection site swelling | 38 | 0 |
| Injection site urticaria | 3 | 0 |
| Injection site vesicles | 7 | 0 |
| Injection site warmth | 11 | 0 |
| Interactions | | |
| Drug interaction | 1 | 0 |
| Mass conditions NEC | | |
| Mass | 1 | 0 |
| Oedema NEC | | |
| Localised oedema | 2 | 0 |
| Oedema | 1 | 0 |
| Oedema peripheral | 2 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 6 | 0 |
| Chest discomfort | 7 | 0 |
| Chest pain | 20 | 0 |
| Discomfort | 8 | 0 |
| Facial pain | 13 | 0 |
| Non-cardiac chest pain | 1 | 0 |
| Pain | 179 | 0 |
| Tenderness | 8 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 52 | 0 |
| Drug ineffective | 7 | 0 |
| No reaction on previous exposure to drug | 1 | 0 |
| Therapeutic product effect incomplete | 1 | 0 |
| Therapeutic response unexpected | 4 | 0 |
| Therapy non-responder | 6 | 0 |
| Vaccination failure | 99 | 0 |
| Vaccination site reactions | | |
| Shoulder injury related to vaccine administration | 1 | 0 |
| Vaccination site bruising | 5 | 0 |
| Vaccination site discolouration | 1 | 0 |
| Vaccination site discomfort | 3 | 0 |
| Vaccination site dryness | 1 | 0 |
| Vaccination site erythema | 38 | 0 |
| Vaccination site hypersensitivity | 1 | 0 |

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|---|-------------|----------|
| General disorders General disorders cont'd | | |
| Vaccination site hypoaesthesia | 1 | 0 |
| Vaccination site induration | 4 | 0 |
| Vaccination site inflammation | 6 | 0 |
| Vaccination site irritation | 2 | 0 |
| Vaccination site joint inflammation | 1 | 0 |
| Vaccination site joint pain | 4 | 0 |
| Vaccination site joint swelling | 1 | 0 |
| Vaccination site mass | 5 | 0 |
| Vaccination site movement impairment | 1 | 0 |
| Vaccination site necrosis | 2 | 0 |
| Vaccination site nodule | 1 | 0 |
| Vaccination site pain | 37 | 0 |
| Vaccination site pallor | 1 | 0 |
| Vaccination site papule | 3 | 0 |
| Vaccination site pruritus | 9 | 0 |
| Vaccination site rash | 17 | 0 |
| Vaccination site reaction | 6 | 0 |
| Vaccination site scar | 1 | 0 |
| Vaccination site swelling | 30 | 0 |
| Vaccination site ulcer | 1 | 0 |
| Vaccination site urticaria | 2 | 0 |
| Vaccination site vesicles | 3 | 0 |
| Vaccination site warmth | 17 | 0 |
| General disorders SOC TOTAL | 1578 | 4 |

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|---|----------|----------|
| Hepatic disorders | | |
| <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 | 3 | 0 |
| Hepatic disorders SOC TOTAL | 5 | 0 |

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|---|-----------|----------|
| Immune system disorders | | |
| <i>Acute and chronic sarcoidosis</i> | | |
| Sarcoidosis | 1 | 0 |
| <i>Allergic conditions NEC</i> | | |
| Hypersensitivity | 17 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 6 | 0 |
| Anaphylactic shock | 1 | 0 |
| Anaphylactoid reaction | 1 | 0 |
| <i>Atopic disorders</i> | | |
| Seasonal allergy | 1 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 1 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Haemophagocytic lymphohistiocytosis | 1 | 0 |
| Immune system disorder | 1 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Immunodeficiency | 2 | 0 |
| <i>Transplant rejections</i> | | |
| Corneal graft rejection | 1 | 0 |
| Immune system disorders SOC TOTAL | 33 | 0 |

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|--|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Diverticulitis | 1 | 0 |
| Gastroenteritis | 1 | 0 |
| <i>Adenoviral infections</i> | | |
| Adenoviral conjunctivitis | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Cellulitis | 12 | 0 |
| Conjunctivitis bacterial | 1 | 0 |
| Folliculitis | 2 | 0 |
| Injection site cellulitis | 2 | 0 |
| Keratitis bacterial | 1 | 0 |
| Skin bacterial infection | 2 | 0 |
| Vaccination site cellulitis | 2 | 0 |
| <i>Bone and joint infections</i> | | |
| Intervertebral discitis | 1 | 0 |
| <i>Candida infections</i> | | |
| Oral candidiasis | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 5 | 0 |
| <i>Coronavirus infections</i> | | |
| COVID-19 | 2 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |
| Gingival abscess | 1 | 0 |
| Gingivitis | 1 | 0 |
| <i>Ear infections</i> | | |
| Labyrinthitis | 3 | 0 |
| Otitis media chronic | 1 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Epstein-Barr virus infection | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 6 | 0 |
| Eye infection | 1 | 0 |
| <i>Fungal infections NEC</i> | | |
| Fungal infection | 2 | 0 |
| <i>Herpes viral infections</i> | | |
| Disseminated varicella | 1 | 0 |
| Disseminated varicella zoster vaccine virus infection | 1 | 0 |
| Eczema herpeticum | 1 | 0 |
| Genital herpes simplex | 2 | 0 |
| Genital herpes zoster | 1 | 0 |
| Herpes ophthalmic | 1 | 0 |
| Herpes simplex | 5 | 0 |
| Herpes zoster | 418 | 0 |
| Herpes zoster cutaneous disseminated | 6 | 0 |
| Herpes zoster disseminated | 2 | 1 |
| Herpes zoster meningoencephalitis | 1 | 0 |
| Herpes zoster necrotising retinopathy | 2 | 0 |
| Herpes zoster oticus | 8 | 0 |
| Meningoencephalitis herpetic | 2 | 0 |
| Ophthalmic herpes simplex | 3 | 0 |
| Ophthalmic herpes zoster | 17 | 0 |
| Oral herpes | 10 | 0 |
| Oral herpes zoster | 1 | 0 |

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| Infections | | |
| Infections cont'd | | |
| Varicella | 65 | 0 |
| Varicella post vaccine | 2 | 0 |
| Varicella zoster virus infection | 8 | 0 |
| Infections NEC | | |
| Abscess | 1 | 0 |
| Infection | 1 | 0 |
| Infection reactivation | 1 | 0 |
| Infection susceptibility increased | 1 | 0 |
| Vaccine breakthrough infection | 1 | 0 |
| Infectious transmissions | | |
| Infection via vaccinee | 4 | 0 |
| Secondary transmission | 9 | 0 |
| Influenza viral infections | | |
| Influenza | 9 | 0 |
| Lower respiratory tract and lung infections | | |
| Lower respiratory tract infection | 6 | 0 |
| Pneumonia | 1 | 0 |
| Pneumonia aspiration | 1 | 0 |
| Mycoplasma infections | | |
| Mycoplasma infection | 1 | 0 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | |
| Sepsis | 1 | 0 |
| Skin structures and soft tissue infections | | |
| 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 |
| Streptococcal infections | | |
| Beta haemolytic streptococcal infection | 1 | 0 |
| Pneumonia pneumococcal | 1 | 0 |
| Upper respiratory tract infections | | |
| Croup infectious | 2 | 0 |
| Laryngitis | 1 | 0 |
| Nasopharyngitis | 5 | 0 |
| Sinusitis | 1 | 0 |
| Upper respiratory tract infection | 1 | 0 |
| Urinary tract infections | | |
| Cystitis | 1 | 0 |
| Urinary tract infection | 2 | 0 |
| Viral infections NEC | | |
| Bronchiolitis | 1 | 0 |
| Encephalitis viral | 1 | 0 |
| Meningoencephalitis viral | 2 | 0 |
| Pleurisy viral | 1 | 0 |
| Post viral fatigue syndrome | 2 | 0 |
| Sweating fever | 1 | 0 |
| Vestibular neuronitis | 1 | 0 |
| Viral infection | 2 | 0 |
| Infections SOC TOTAL | 684 | 1 |

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|--|-------|-------|
| Injuries | | |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 2 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 4 | 0 |
| Foetal exposure during pregnancy | 1 | 0 |
| Maternal exposure before pregnancy | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Medication error | 17 | 0 |
| Product use in unapproved indication | 1 | 0 |
| Product use issue | 2 | 0 |
| Vaccination error | 5 | 0 |
| Wrong technique in product usage process | 3 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 6 | 0 |
| Nerve root injury | 1 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Eschar | 1 | 0 |
| Fall | 3 | 0 |
| Wound secretion | 1 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Infusion related reaction | 1 | 0 |
| <i>Occupational exposures</i> | | |
| Occupational exposure to product | 5 | 0 |
| <i>Off label uses</i> | | |
| Off label use | 1 | 0 |
| <i>Overdoses NEC</i> | | |
| Overdose | 1 | 0 |
| <i>Pathways and sources of exposure</i> | | |
| Exposure via skin contact | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Contraindicated product administered | 4 | 0 |
| Extra dose administered | 2 | 0 |
| Inappropriate schedule of product administration | 3 | 0 |
| Incomplete course of vaccination | 1 | 0 |
| Incorrect dose administered | 1 | 0 |
| Incorrect route of product administration | 11 | 0 |
| Product administered at inappropriate site | 5 | 0 |
| Product administered to patient of inappropriate age | 4 | 0 |
| Product administration error | 2 | 0 |
| Product dose omission issue | 1 | 0 |
| Wrong product administered | 4 | 0 |
| <i>Product monitoring errors and issues</i> | | |
| Labelled drug-disease interaction medication error | 1 | 0 |
| <i>Product prescribing errors and issues</i> | | |
| Product prescribing error | 1 | 0 |
| <i>Product storage errors and issues in the product use system</i> | | |
| Product storage error | 2 | 0 |
| <i>Site specific injuries NEC</i> | | |
| Limb injury | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 9 | 0 |
| Scar | 2 | 0 |
| Skin abrasion | 3 | 0 |

Case Series Drug Analysis Print

Name: Shingles vaccine analysis print

Report Run Date: 15-May-2023
Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Injuries Injuries cont'd | | |
| Skin laceration | 1 | 0 |
| Thoracic cage fractures and dislocations | | |
| Rib fracture | 1 | 0 |
| Underdoses NEC | | |
| Underdose | 1 | 0 |
| Vaccination related complications | | |
| Immunisation reaction | 2 | 0 |
| Post vaccination syndrome | 1 | 0 |
| Injuries SOC TOTAL | 120 | 0 |

Case Series Drug Analysis Print

Name: Shingles vaccine analysis print

Report Run Date: 15-May-2023
Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Investigations | | |
| <i>Blood gas and acid base analyses</i> | | |
| Oxygen saturation decreased | 2 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose increased | 2 | 0 |
| <i>Cell marker analyses</i> | | |
| Prostatic specific antigen increased | 1 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Inflammatory marker increased | 1 | 0 |
| <i>Coagulation and bleeding analyses</i> | | |
| International normalised ratio increased | 1 | 0 |
| <i>ECG investigations</i> | | |
| Electrocardiogram QT prolonged | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate increased | 7 | 0 |
| Heart rate irregular | 3 | 0 |
| Pulse abnormal | 1 | 0 |
| <i>Hepatobiliary function diagnostic procedures</i> | | |
| Liver function test abnormal | 4 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Antibody test negative | 2 | 0 |
| <i>Microbiology and serology tests NEC</i> | | |
| Serology negative | 1 | 0 |
| <i>Ophthalmic function diagnostic procedures</i> | | |
| Intraocular pressure increased | 2 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature | 1 | 0 |
| Body temperature decreased | 3 | 0 |
| Body temperature fluctuation | 2 | 0 |
| Body temperature increased | 15 | 0 |
| Neurological examination abnormal | 1 | 0 |
| Respiratory rate increased | 1 | 0 |
| Weight decreased | 3 | 0 |
| <i>Pituitary analyses anterior</i> | | |
| Blood thyroid stimulating hormone decreased | 1 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count decreased | 1 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein increased | 5 | 0 |
| <i>Renal function analyses</i> | | |
| Blood creatinine increased | 1 | 0 |
| <i>Urinary tract function analyses NEC</i> | | |
| Urine output decreased | 1 | 0 |
| Urine output increased | 1 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure increased | 5 | 0 |
| <i>Virus identification and serology</i> | | |
| SARS-CoV-2 test positive | 2 | 0 |
| Varicella virus test negative | 1 | 0 |
| <i>White blood cell analyses</i> | | |
| Neutrophil count decreased | 1 | 0 |
| White blood cell count increased | 1 | 0 |
| Investigations SOC TOTAL | 74 | 0 |

Case Series Drug Analysis Print

Name: Shingles vaccine analysis print

Report Run Date: 15-May-2023
 Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
 MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 28 | 0 |
| Food refusal | 1 | 0 |
| Hypophagia | 2 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Type 2 diabetes mellitus | 1 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 2 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Alcohol intolerance | 1 | 0 |
| Food intolerance | 1 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 4 | 0 |
| Feeding disorder | 1 | 0 |
| <i>Sodium imbalance</i> | | |
| Hyponatraemia | 1 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 3 | 0 |
| Metabolic disorders SOC TOTAL | 45 | 0 |

Case Series Drug Analysis Print

Name: Shingles vaccine analysis print

Report Run Date: 15-May-2023
Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 5 | 0 |
| Arthropathy | 2 | 0 |
| Polyarthritis | 2 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 2 | 0 |
| Pain in jaw | 4 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 2 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Polymyalgia rheumatica | 20 | 0 |
| Scleroderma | 1 | 0 |
| <i>Extremity deformities</i> | | |
| Hand deformity | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Periarthritis | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 119 | 0 |
| Joint stiffness | 4 | 0 |
| Joint swelling | 17 | 0 |
| <i>Ligament disorders</i> | | |
| Ligament pain | 1 | 0 |
| <i>Lupus erythematosus (incl subtypes)</i> | | |
| Systemic lupus erythematosus | 4 | 0 |
| <i>Muscle infections and inflammations</i> | | |
| Myositis | 1 | 0 |
| Polymyositis | 1 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 107 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle fatigue | 2 | 0 |
| Muscle spasms | 7 | 0 |
| Muscle tightness | 2 | 0 |
| Muscle twitching | 3 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Floppy infant | 1 | 0 |
| Muscle rigidity | 1 | 0 |
| Torticollis | 2 | 0 |
| Trismus | 1 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 25 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Limb mass | 1 | 0 |
| Mobility decreased | 4 | 0 |
| Musculoskeletal stiffness | 16 | 0 |
| Weight bearing difficulty | 1 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 40 | 0 |
| Limb discomfort | 8 | 0 |
| Musculoskeletal chest pain | 7 | 0 |
| Musculoskeletal discomfort | 5 | 0 |
| Musculoskeletal pain | 5 | 0 |
| Neck pain | 17 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
 Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
 MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Pain in extremity | 137 | 0 |
| <i>Osteoarthropathies</i> | | |
| Osteoarthritis | 2 | 0 |
| <i>Rheumatoid arthropathies</i> | | |
| Rheumatoid arthritis | 4 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Axillary mass | 1 | 0 |
| Groin pain | 9 | 0 |
| Soft tissue disorder | 1 | 0 |
| <i>Spine and neck deformities</i> | | |
| Spinal stenosis | 1 | 0 |
| <i>Spondyloarthropathies</i> | | |
| Arthritis reactive | 2 | 0 |
| Spondyloarthropathy | 1 | 0 |
| <i>Tendon disorders</i> | | |
| Tendon pain | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 601 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
 Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
 MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|---|----------|----------|
| Neoplasms | | |
| <i>B-cell small lymphocytic lymphomas</i> | | |
| B-cell small lymphocytic lymphoma | 1 | 0 |
| <i>Breast and nipple neoplasms malignant</i> | | |
| Breast cancer in situ | 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 |
| Neoplasms SOC TOTAL | 8 | 1 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Areflexia | 2 | 0 |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 2 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Acute polyneuropathy | 1 | 0 |
| Guillain-Barre syndrome | 10 | 1 |
| Miller Fisher syndrome | 1 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Cerebral infarction | 1 | 0 |
| Cerebrovascular accident | 4 | 0 |
| <i>Central nervous system inflammatory disorders NEC</i> | | |
| Central nervous system inflammation | 1 | 0 |
| <i>Chronic polyneuropathies</i> | | |
| Demyelinating polyneuropathy | 1 | 0 |
| <i>Coma states</i> | | |
| Coma | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Ataxia | 3 | 0 |
| Balance disorder | 14 | 0 |
| Coordination abnormal | 4 | 0 |
| Dysstasia | 1 | 0 |
| Nystagmus | 1 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 2 | 0 |
| <i>Demyelinating disorders NEC</i> | | |
| Acute disseminated encephalomyelitis | 1 | 1 |
| <i>Disturbances in consciousness NEC</i> | | |
| Consciousness fluctuating | 1 | 0 |
| Depressed level of consciousness | 2 | 0 |
| Lethargy | 29 | 0 |
| Loss of consciousness | 3 | 0 |
| Postictal state | 1 | 0 |
| Somnolence | 17 | 0 |
| Syncope | 19 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Dyskinesia | 1 | 0 |
| Fine motor skill dysfunction | 1 | 0 |
| Hypokinesia | 1 | 0 |
| Movement disorder | 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> | | |
| Microvascular cranial nerve palsy | 1 | 0 |
| VIth nerve paralysis | 1 | 0 |
| <i>Facial cranial nerve disorders</i> | | |
| Bell's palsy | 16 | 0 |
| Facial paralysis | 10 | 0 |
| Facial paresis | 1 | 0 |
| <i>Generalised tonic-clonic seizures</i> | | |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Generalised tonic-clonic seizure | 1 | 0 |
| Headaches NEC | | |
| Cluster headache | 2 | 0 |
| Headache | 192 | 0 |
| Occipital neuralgia | 1 | 0 |
| Tension headache | 3 | 0 |
| Increased intracranial pressure disorders | | |
| Brain oedema | 1 | 0 |
| Lumbar spinal cord and nerve root disorders | | |
| Sciatica | 6 | 0 |
| Memory loss (excl dementia) | | |
| Amnesia | 4 | 0 |
| Memory impairment | 3 | 0 |
| Transient global amnesia | 1 | 0 |
| Mental impairment (excl dementia and memory loss) | | |
| Cognitive disorder | 1 | 0 |
| Disturbance in attention | 5 | 0 |
| Mental impairment | 1 | 0 |
| Migraine headaches | | |
| Migraine | 4 | 0 |
| Mononeuropathies | | |
| Sciatic nerve neuropathy | 1 | 0 |
| Motor neurone diseases | | |
| Motor neurone disease | 1 | 1 |
| Multiple sclerosis acute and progressive | | |
| Multiple sclerosis | 1 | 0 |
| Multiple sclerosis relapse | 1 | 0 |
| Muscle tone abnormal | | |
| Hypotonia | 4 | 0 |
| Narcolepsy and hypersomnia | | |
| Hypersomnia | 4 | 0 |
| Nervous system disorders NEC | | |
| Central nervous system lesion | 1 | 0 |
| Cerebral disorder | 2 | 0 |
| Nervous system disorder | 4 | 0 |
| Neurological signs and symptoms NEC | | |
| Brain fog | 2 | 0 |
| Dizziness | 65 | 0 |
| Dizziness postural | 2 | 0 |
| Head discomfort | 4 | 0 |
| Meningism | 1 | 0 |
| Presyncope | 3 | 0 |
| Unresponsive to stimuli | 3 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning sensation | 18 | 0 |
| Formication | 4 | 0 |
| Hyperaesthesia | 11 | 0 |
| Hypoaesthesia | 27 | 0 |
| Paraesthesia | 63 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Hemiparesis | 2 | 0 |
| Monoparesis | 1 | 0 |
| Monoplegia | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
Earliest Reaction Date: 14-Jan-2005

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| <i>Partial complex seizures</i> | | |
| Dreamy state | 1 | 0 |
| <i>Peripheral neuropathies NEC</i> | | |
| Neuralgic amyotrophy | 3 | 0 |
| Neuritis | 2 | 0 |
| Neuropathy peripheral | 3 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Epilepsy | 2 | 0 |
| Febrile convulsion | 2 | 0 |
| Seizure | 10 | 0 |
| <i>Sensory abnormalities NEC</i> | | |
| Ageusia | 1 | 0 |
| Allodynia | 2 | 0 |
| Dysgeusia | 6 | 0 |
| Electric shock sensation | 6 | 0 |
| Neuralgia | 55 | 0 |
| Post herpetic neuralgia | 26 | 0 |
| Sensory disturbance | 4 | 0 |
| Sensory loss | 2 | 0 |
| Taste disorder | 1 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Dysarthria | 8 | 0 |
| Incoherent | 1 | 0 |
| Language disorder | 1 | 0 |
| Slow speech | 1 | 0 |
| Speech disorder | 3 | 0 |
| <i>Spinal cord and nerve root disorders NEC</i> | | |
| Radiculitis brachial | 1 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Tremor | 19 | 0 |
| <i>Trigeminal disorders</i> | | |
| Trigeminal neuralgia | 5 | 0 |
| Nervous system disorders SOC TOTAL | 776 | 3 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Pregnancy conditions | | |
| <i>Hypertension associated disorders of pregnancy</i> | | |
| Pre-eclampsia | 1 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Induced labour | 1 | 0 |
| Premature delivery | 1 | 0 |
| Premature rupture of membranes | 1 | 0 |
| Prolonged labour | 1 | 0 |
| Prolonged pregnancy | 1 | 0 |
| <i>Maternal complications of labour NEC</i> | | |
| Labour complication | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 7 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--------------------------|----------|----------|
| <i>Device issues NEC</i> | | |
| Device connection issue | 3 | 0 |
| null SOC TOTAL | 3 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 2 | 0 |
| Staring | 3 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 5 | 0 |
| Anxiety | 5 | 0 |
| Immunisation stress-related response | 1 | 0 |
| Nervousness | 2 | 0 |
| Stress | 4 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Paranoia | 1 | 0 |
| Social avoidant behaviour | 1 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |
| Mental fatigue | 1 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 17 | 0 |
| Disorientation | 8 | 0 |
| <i>Decreased physical activity levels</i> | | |
| Catatonia | 1 | 0 |
| <i>Deliria</i> | | |
| Delirium | 2 | 0 |
| <i>Depressive disorders</i> | | |
| Depression | 4 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 13 | 0 |
| <i>Dyssomnias</i> | | |
| Poor quality sleep | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 2 | 0 |
| Emotional disorder | 1 | 0 |
| Irritability | 6 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Fear | 1 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 3 | 0 |
| Hallucination, visual | 3 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 1 | 0 |
| <i>Mental disorders due to a general medical condition NEC</i> | | |
| Neuropsychiatric symptoms | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Decreased interest | 1 | 0 |
| Depressed mood | 2 | 0 |
| Feeling of despair | 1 | 0 |
| Tearfulness | 2 | 0 |
| <i>Mood disorders NEC</i> | | |
| Listless | 3 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Panic attack | 1 | 0 |
| <i>Parasomnias</i> | | |
| Nightmare | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Rapid eye movements sleep abnormal | 1 | 0 |
| Perception disturbances NEC | | |
| Illusion | 2 | 0 |
| Near death experience | 1 | 0 |
| Psychiatric symptoms NEC | | |
| Psychiatric symptom | 1 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 8 | 0 |
| Stereotypies and automatisms | | |
| Bruxism | 1 | 0 |
| Thinking disturbances | | |
| Impaired reasoning | 1 | 0 |
| Tic disorders | | |
| Tic | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 117 | 0 |

Case Series Drug Analysis Print

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 Earliest Reaction Date: 14-Jan-2005

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Dysuria | 1 | 0 |
| Incontinence | 1 | 0 |
| Micturition disorder | 1 | 0 |
| Micturition urgency | 1 | 0 |
| Pollakiuria | 7 | 0 |
| Urinary incontinence | 4 | 0 |
| Urinary retention | 2 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder disorder | 1 | 0 |
| <i>Genital and urinary tract disorders NEC</i> | | |
| Urinary tract disorder | 1 | 0 |
| <i>Renal disorders NEC</i> | | |
| Renal disorder | 1 | 0 |
| Single functional kidney | 1 | 0 |
| <i>Renal failure and impairment</i> | | |
| Renal failure | 2 | 0 |
| Renal impairment | 2 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 4 | 0 |
| Haematuria | 1 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Costovertebral angle tenderness | 1 | 0 |
| Renal pain | 4 | 0 |
| Renal & urinary disorders SOC TOTAL | 35 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
 Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Reproductive & breast disorders | | |
| <i>Breast signs and symptoms</i> | | |
| Breast pain | 2 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Menstruation irregular | 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 |
| Reproductive & breast disorders SOC TOTAL | 10 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 1 | 0 |
| Dyspnoea | 18 | 0 |
| Grunting | 1 | 0 |
| Hypopnoea | 2 | 0 |
| Respiration abnormal | 1 | 0 |
| Respiratory arrest | 1 | 0 |
| Tachypnoea | 1 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchiectasis | 1 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 4 | 0 |
| Chronic obstructive pulmonary disease | 2 | 0 |
| Wheezing | 3 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 17 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 1 | 0 |
| Pneumonitis | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 4 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 2 | 0 |
| Nasal disorder | 1 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Sinonasal obstruction | 1 | 0 |
| Sinus congestion | 2 | 0 |
| Sinus disorder | 1 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Interstitial lung disease | 1 | 0 |
| Lung consolidation | 1 | 0 |
| Organising pneumonia | 1 | 0 |
| Pulmonary alveolar haemorrhage | 1 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal paraesthesia | 1 | 0 |
| Pharyngeal swelling | 3 | 0 |
| Tonsillar ulcer | 1 | 0 |
| <i>Pleural conditions NEC</i> | | |
| Pleural adhesion | 1 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Pleural effusion | 1 | 0 |
| <i>Pulmonary hypertensions</i> | | |
| Pulmonary hypertension | 1 | 0 |
| <i>Pulmonary oedemas</i> | | |
| Acute lung injury | 1 | 0 |
| Acute respiratory distress syndrome | 1 | 0 |
| Pulmonary congestion | 1 | 0 |
| Pulmonary oedema | 1 | 0 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary embolism | 1 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Respiratory failure | 2 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |

Case Series Drug Analysis Print

Name: Shingles vaccine analysis print

Report Run Date: 15-May-2023
 Earliest Reaction Date: 14-Jan-2005

Data Lock Date: 12-May-2023 16:30:03
 MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Respiratory disorder | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 1 | 0 |
| Catarrh | 1 | 0 |
| Choking sensation | 1 | 0 |
| Dry throat | 2 | 0 |
| Dysphonia | 2 | 0 |
| Increased upper airway secretion | 1 | 0 |
| Oropharyngeal discomfort | 1 | 0 |
| Oropharyngeal pain | 18 | 0 |
| Rhinorrhoea | 7 | 0 |
| Sinus pain | 1 | 0 |
| Sneezing | 1 | 0 |
| Throat irritation | 1 | 0 |
| Throat tightness | 3 | 0 |
| Upper-airway cough syndrome | 1 | 0 |
| Yawning | 2 | 0 |
| Respiratory disorders SOC TOTAL | 128 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
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MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 3 | 0 |
| Dermatitis acneiform | 1 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 2 | 0 |
| Alopecia totalis | 1 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 5 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 7 | 0 |
| Hyperhidrosis | 12 | 0 |
| Miliaria | 1 | 0 |
| Night sweats | 7 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 70 | 0 |
| Dermatitis bullous | 3 | 0 |
| Erythema multiforme | 2 | 0 |
| Pemphigoid | 1 | 0 |
| Stevens-Johnson syndrome | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 11 | 0 |
| Macule | 2 | 0 |
| Pain of skin | 17 | 0 |
| Papule | 21 | 0 |
| Scab | 13 | 0 |
| Sensitive skin | 7 | 0 |
| Skin burning sensation | 5 | 0 |
| Skin discolouration | 3 | 0 |
| Skin discomfort | 3 | 0 |
| Skin disorder | 2 | 0 |
| Skin lesion | 15 | 0 |
| Skin reaction | 12 | 0 |
| Skin sensitisation | 5 | 0 |
| Skin texture abnormal | 1 | 0 |
| Skin warm | 16 | 0 |
| Skin weeping | 1 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 7 | 0 |
| Dermatitis allergic | 13 | 0 |
| Dermatitis diaper | 1 | 0 |
| Eczema | 11 | 0 |
| Intertrigo | 1 | 0 |
| Skin irritation | 16 | 0 |
| Stasis dermatitis | 1 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 3 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 104 | 0 |
| <i>Exfoliative conditions</i> | | |
| Skin exfoliation | 9 | 0 |
| <i>Granulomatous and deep cutaneous inflammatory conditions</i> | | |
| Granuloma annulare | 1 | 0 |
| <i>Hyperkeratoses</i> | | |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Hyperkeratosis | 1 | 0 |
| Panniculitides | | |
| Erythema nodosum | 1 | 0 |
| Papulosquamous conditions | | |
| Lichen planus | 3 | 0 |
| Pityriasis rubra pilaris | 1 | 0 |
| Photosensitivity and photodermatosis conditions | | |
| Photosensitivity reaction | 1 | 0 |
| Solar dermatitis | 1 | 0 |
| Pigmentation changes NEC | | |
| Pigmentation disorder | 1 | 0 |
| Pruritus NEC | | |
| Pruritus | 158 | 0 |
| Psoriatic conditions | | |
| Psoriasis | 4 | 0 |
| Pustular psoriasis | 1 | 0 |
| Purpura and related conditions | | |
| Petechiae | 4 | 0 |
| Purpura | 6 | 0 |
| Pustular conditions | | |
| Acute generalised exanthematous pustulosis | 1 | 0 |
| Rashes, eruptions and exanths NEC | | |
| Nodular rash | 1 | 0 |
| Rash | 203 | 0 |
| Rash erythematous | 44 | 0 |
| Rash macular | 17 | 0 |
| Rash maculo-papular | 15 | 0 |
| Rash morbilliform | 2 | 0 |
| Rash papular | 28 | 0 |
| Rash pruritic | 49 | 0 |
| Rash vesicular | 167 | 0 |
| Rosaceas | | |
| Rosacea | 1 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Skin mass | 1 | 0 |
| Skin and subcutaneous tissue ulcerations | | |
| Skin ulcer | 1 | 0 |
| Skin haemorrhages | | |
| Haemorrhage subcutaneous | 1 | 0 |
| Skin haemorrhage | 3 | 0 |
| Skin hyperplasias and hypertrophies | | |
| Skin hypertrophy | 1 | 0 |
| Skin vasculitides | | |
| Hypersensitivity vasculitis | 4 | 0 |
| Vasculitic rash | 5 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 3 | 0 |
| Urticarias | | |
| Urticaria | 50 | 0 |
| Skin disorders SOC TOTAL | 1196 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 26.0

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Social circumstances | | |
| <i>Disability issues</i> | | |
| Bedridden | 2 | 0 |
| Loss of personal independence in daily activities | 5 | 0 |
| <i>Social issues NEC</i> | | |
| Contraindication to vaccination | 10 | 0 |
| Impaired quality of life | 1 | 0 |
| Social circumstances SOC TOTAL | 18 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|--------------|--------------|
| Surgical & medical procedures | | |
| <i>Obstetric therapeutic procedures</i> | | |
| Caesarean section | 4 | 0 |
| <i>Renal therapeutic procedures</i> | | |
| Renal transplant | 1 | 0 |
| <i>Therapeutic procedures NEC</i> | | |
| Rest regimen | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 6 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 15-May-2023
Earliest Reaction Date: 14-Jan-2005

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| Reaction Name | Total | Fatal |
|---|--------------|--------------|
| Vascular disorders | | |
| <i>Arterial infections and inflammations</i> | | |
| Giant cell arteritis | 1 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 4 | 0 |
| Shock | 1 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Thrombosis | 1 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Endothelial dysfunction | 1 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | |
| Deep vein thrombosis | 2 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 2 | 0 |
| Flushing | 5 | 0 |
| Hot flush | 4 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 2 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 12 | 0 |
| <i>Varicose veins NEC</i> | | |
| Varicose vein | 1 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 6 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Hypotension | 2 | 0 |
| <i>Vasculitides NEC</i> | | |
| Vasculitis | 1 | 0 |
| Vascular disorders SOC TOTAL | 45 | 0 |
| TOTAL REACTIONS FOR DRUG | 6117 | 14 |
| TOTAL REPORTS | 2185 | |
| TOTAL FATAL OUTCOME REPORTS | | 14 |