

Case Series Drug Analysis Print
Name: Revaxis Vaccine Analysis Print

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 24-Feb-2004

MedDRA Version: MedDRA 25.1

Revaxis Vaccine Analysis Print: All UK spontaneous ADR reports for Revaxis since the start of the Yellow Card system to 11/11/2022

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Blood disorders | | |
| <i>Anaemias NEC</i> | | |
| Anaemia | 1 | 0 |
| <i>Bleeding tendencies</i> | | |
| Haemorrhagic disorder | 1 | 0 |
| <i>Coagulopathies</i> | | |
| Coagulopathy | 2 | 0 |
| Disseminated intravascular coagulation | 1 | 0 |
| <i>Leukocytoses NEC</i> | | |
| Leukocytosis | 1 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Lymphadenitis | 2 | 0 |
| Lymphadenopathy | 35 | 0 |
| <i>Marrow depression and hypoplastic anaemias</i> | | |
| Aplastic anaemia | 2 | 1 |
| Pancytopenia | 1 | 0 |
| <i>Neutropenias</i> | | |
| Neutropenia | 4 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 2 | 0 |
| Thrombocytopenia | 1 | 0 |
| Blood disorders SOC TOTAL | 53 | 1 |

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|---------------------------------------|-----------|----------|
| Cardiac disorders | | |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Palpitations | 6 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Arteriosclerosis coronary artery | 1 | 0 |
| <i>Left ventricular failures</i> | | |
| Left ventricular failure | 1 | 1 |
| <i>Myocardial disorders NEC</i> | | |
| Cardiomegaly | 1 | 0 |
| Left ventricular dysfunction | 1 | 0 |
| <i>Pericardial disorders NEC</i> | | |
| Pericardial effusion | 1 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Arrhythmia | 2 | 0 |
| Bradycardia | 3 | 0 |
| Tachycardia | 22 | 0 |
| <i>Supraventricular arrhythmias</i> | | |
| Atrial fibrillation | 1 | 0 |
| Supraventricular tachycardia | 1 | 0 |
| Cardiac disorders SOC TOTAL | 40 | 1 |

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|--|----------|----------|
| Congenital disorders | | |
| <i>Autosomal chromosomal abnormalities</i> | | |
| Trisomy 21 | 1 | 0 |
| <i>Congenital disorders NEC</i> | | |
| Congenital cyst | 1 | 0 |
| <i>Musculoskeletal and connective tissue disorders of limbs congenital</i> | | |
| Syndactyly | 1 | 0 |
| <i>Musculoskeletal and connective tissue disorders of skull congenital</i> | | |
| Plagiocephaly | 1 | 0 |
| <i>Neurological disorders congenital NEC</i> | | |
| Tourette's disorder | 1 | 0 |
| <i>Skin and subcutaneous tissue disorders congenital NEC</i> | | |
| Congenital skin dimples | 1 | 0 |
| <i>Tongue disorders congenital</i> | | |
| Ankyloglossia congenital | 1 | 0 |
| Congenital disorders SOC TOTAL | 7 | 0 |

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|---|-----------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear discomfort | 3 | 0 |
| Ear pain | 3 | 0 |
| Ear swelling | 1 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 2 | 0 |
| Deafness neurosensory | 1 | 0 |
| Deafness unilateral | 1 | 0 |
| Hypoacusis | 7 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Vestibular disorder | 1 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Tinnitus | 5 | 0 |
| Vertigo | 12 | 0 |
| Vertigo positional | 1 | 0 |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane perforation | 1 | 0 |
| Ear disorders SOC TOTAL | 38 | 0 |

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|--------------------------------------|----------|----------|
| Endocrine disorders | | |
| <i>Adrenal gland disorders NEC</i> | | |
| Adrenal disorder | 1 | 0 |
| Endocrine disorders SOC TOTAL | 1 | 0 |

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|---|------------|----------|
| Eye disorders | | |
| <i>Conjunctival infections, irritations and inflammations</i> | | |
| Conjunctivitis allergic | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 1 | 0 |
| <i>Lacrimation disorders</i> | | |
| Lacrimation increased | 1 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Erythema of eyelid | 1 | 0 |
| Eyelid oedema | 2 | 0 |
| Swelling of eyelid | 6 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye pain | 12 | 0 |
| Eye swelling | 19 | 0 |
| Periorbital swelling | 1 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye irritation | 5 | 0 |
| Eye pruritus | 5 | 0 |
| Ocular hyperaemia | 8 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Binocular eye movement disorder | 1 | 0 |
| Eye movement disorder | 31 | 0 |
| Gaze palsy | 2 | 0 |
| Strabismus | 1 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Asthenopia | 3 | 0 |
| Photophobia | 27 | 0 |
| <i>Orbital infections, inflammations and irritations</i> | | |
| Parophthalmia | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Mydriasis | 11 | 0 |
| Pupil fixed | 2 | 0 |
| <i>Retinal, choroid and vitreous infections and inflammations</i> | | |
| Retinal vasculitis | 1 | 0 |
| <i>Visual colour distortions</i> | | |
| Xanthopsia | 1 | 0 |
| <i>Visual disorders NEC</i> | | |
| Diplopia | 3 | 0 |
| Photopsia | 3 | 0 |
| Vision blurred | 33 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Amaurosis fugax | 1 | 0 |
| Blindness | 3 | 0 |
| Blindness transient | 2 | 0 |
| Visual impairment | 11 | 0 |
| Eye disorders SOC TOTAL | 199 | 0 |

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|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Acute and chronic pancreatitis</i> | | |
| Pancreatitis | 1 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Colitis ulcerative | 2 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Hyperaesthesia teeth | 1 | 0 |
| <i>Dental surface disorders</i> | | |
| Tooth discolouration | 1 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 71 | 0 |
| Diarrhoea haemorrhagic | 1 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Faeces pale | 1 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 36 | 0 |
| Abdominal pain lower | 1 | 0 |
| Abdominal pain upper | 48 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 2 | 0 |
| Gastrooesophageal reflux disease | 3 | 0 |
| Impaired gastric emptying | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Gastrointestinal disorder | 2 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 12 | 0 |
| Anal incontinence | 1 | 0 |
| Dysphagia | 11 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Frequent bowel movements | 2 | 0 |
| Irritable bowel syndrome | 1 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival pain | 1 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Rectal haemorrhage | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 346 | 0 |
| Retching | 2 | 0 |
| Vomiting | 223 | 0 |
| Vomiting projectile | 2 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Haematemesis | 1 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Dry mouth | 2 | 0 |
| Salivary hypersecretion | 1 | 0 |
| <i>Oral soft tissue disorders NEC</i> | | |
| Chapped lips | 1 | 0 |
| Oral disorder | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Hypoaesthesia oral | 4 | 0 |
| Oral discomfort | 1 | 0 |
| Oral pain | 3 | 0 |

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| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Oral pruritus | 2 | 0 |
| Paraesthesia oral | 16 | 0 |
| Oral soft tissue swelling and oedema | | |
| Lip swelling | 23 | 0 |
| Mouth swelling | 3 | 0 |
| Salivary gland enlargements | | |
| Parotid gland enlargement | 1 | 0 |
| Stomatitis and ulceration | | |
| Mouth ulceration | 1 | 0 |
| Stomatitis | 1 | 0 |
| Tongue disorders | | |
| Glossitis | 1 | 0 |
| Tongue disorder | 1 | 0 |
| Tongue signs and symptoms | | |
| Swollen tongue | 11 | 0 |
| Tongue discolouration | 1 | 0 |
| Tongue movement disturbance | 1 | 0 |
| Umbilical hernias | | |
| Umbilical hernia | 2 | 0 |
| Gastrointestinal disorders SOC TOTAL | 852 | 0 |

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|--|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site bruise | 1 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site erythema | 1 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 45 | 0 |
| Chronic fatigue syndrome | 1 | 0 |
| Fatigue | 134 | 0 |
| Malaise | 357 | 0 |
| <i>Febrile disorders</i> | | |
| Hyperpyrexia | 2 | 0 |
| Pyrexia | 500 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 92 | 0 |
| Feeling abnormal | 21 | 0 |
| Feeling cold | 22 | 0 |
| Feeling hot | 85 | 0 |
| Feeling of body temperature change | 21 | 0 |
| Sensation of foreign body | 2 | 0 |
| Thirst | 3 | 0 |
| Thirst decreased | 1 | 0 |
| <i>Gait disturbances</i> | | |
| Gait disturbance | 8 | 0 |
| Gait inability | 4 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Condition aggravated | 7 | 0 |
| Crepitations | 2 | 0 |
| Crying | 7 | 0 |
| Developmental delay | 1 | 0 |
| Effusion | 1 | 0 |
| Illness | 48 | 0 |
| Induration | 3 | 0 |
| Influenza like illness | 86 | 0 |
| Irritability postvaccinal | 1 | 0 |
| Local reaction | 24 | 0 |
| Multiple organ dysfunction syndrome | 1 | 0 |
| Peripheral swelling | 73 | 0 |
| Screaming | 1 | 0 |
| Swelling | 39 | 0 |
| Swelling face | 26 | 0 |
| <i>Inflammations</i> | | |
| Inflammation | 16 | 0 |
| Systemic inflammatory response syndrome | 2 | 0 |
| <i>Infusion site reactions</i> | | |
| Infusion site discomfort | 1 | 0 |
| <i>Injection site reactions</i> | | |
| Injected limb mobility decreased | 3 | 0 |
| Injection site bruising | 3 | 0 |
| Injection site coldness | 1 | 0 |
| Injection site discolouration | 2 | 0 |
| Injection site discomfort | 1 | 0 |
| Injection site erythema | 33 | 0 |
| Injection site haemorrhage | 3 | 0 |

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|---|-------|-------|
| General disorders General disorders cont'd | | |
| Injection site hypersensitivity | 1 | 0 |
| Injection site induration | 4 | 0 |
| Injection site inflammation | 8 | 0 |
| Injection site irritation | 1 | 0 |
| Injection site mass | 7 | 0 |
| Injection site movement impairment | 3 | 0 |
| Injection site necrosis | 1 | 0 |
| Injection site nodule | 1 | 0 |
| Injection site pain | 25 | 0 |
| Injection site paraesthesia | 1 | 0 |
| Injection site pruritus | 8 | 0 |
| Injection site rash | 12 | 0 |
| Injection site reaction | 17 | 0 |
| Injection site swelling | 24 | 0 |
| Injection site urticaria | 1 | 0 |
| Injection site vesicles | 1 | 0 |
| Injection site warmth | 5 | 0 |
| Mass conditions NEC | | |
| Cyst | 1 | 0 |
| Mass | 4 | 0 |
| Oedema NEC | | |
| Face oedema | 5 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 9 | 0 |
| Chest discomfort | 20 | 0 |
| Chest pain | 25 | 0 |
| Discomfort | 9 | 0 |
| Facial pain | 1 | 0 |
| Pain | 107 | 0 |
| Tenderness | 11 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 6 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 2 | 0 |
| Shoulder injury related to vaccine administration | 1 | 0 |
| Vaccination site bruising | 3 | 0 |
| Vaccination site discomfort | 1 | 0 |
| Vaccination site eczema | 1 | 0 |
| Vaccination site erythema | 23 | 0 |
| Vaccination site induration | 2 | 0 |
| Vaccination site inflammation | 5 | 0 |
| Vaccination site joint pain | 2 | 0 |
| Vaccination site mass | 2 | 0 |
| Vaccination site movement impairment | 3 | 0 |
| Vaccination site nodule | 1 | 0 |
| Vaccination site pain | 38 | 0 |
| Vaccination site papule | 1 | 0 |
| Vaccination site paraesthesia | 1 | 0 |
| Vaccination site pruritus | 2 | 0 |
| Vaccination site rash | 3 | 0 |
| Vaccination site reaction | 4 | 0 |
| Vaccination site scab | 1 | 0 |
| Vaccination site swelling | 27 | 0 |

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|---|-------------|----------|
| General disorders General disorders cont'd | | |
| Vaccination site vesicles | 1 | 0 |
| Vaccination site warmth | 6 | 0 |
| General disorders SOC TOTAL | 2133 | 0 |

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|--|-----------|----------|
| Hepatic disorders | | |
| <i>Bile duct infections and inflammations</i> | | |
| Cholangitis sclerosing | 1 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 11 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hepatic function abnormal | 2 | 0 |
| Hypertransaminasaemia | 1 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Acute hepatic failure | 1 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatomegaly | 1 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Autoimmune hepatitis | 1 | 0 |
| Hepatitis acute | 2 | 0 |
| Liver injury | 1 | 0 |
| Hepatic disorders SOC TOTAL | 21 | 0 |

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|---|------------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Allergy to animal | 1 | 0 |
| Hypersensitivity | 31 | 0 |
| Mite allergy | 1 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergic reaction to excipient | 1 | 0 |
| Allergy to vaccine | 2 | 0 |
| Food allergy | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 54 | 0 |
| Anaphylactic shock | 2 | 0 |
| Anaphylactoid reaction | 1 | 0 |
| <i>Atopic disorders</i> | | |
| Seasonal allergy | 1 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 2 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Bacille Calmette-Guerin scar reactivation | 1 | 0 |
| Haemophagocytic lymphohistiocytosis | 1 | 1 |
| Immune system disorder | 1 | 0 |
| Immune-mediated adverse reaction | 1 | 0 |
| Immunisation reaction | 4 | 0 |
| Multisystem inflammatory syndrome in children | 1 | 0 |
| Immune system disorders SOC TOTAL | 106 | 1 |

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|---|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Appendicitis perforated | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Arthritis bacterial | 1 | 0 |
| Cellulitis | 9 | 0 |
| Injection site cellulitis | 2 | 0 |
| Meningitis bacterial | 1 | 0 |
| Tonsillitis bacterial | 1 | 0 |
| <i>Bordetella infections</i> | | |
| Pertussis | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 1 | 0 |
| Meningitis | 1 | 0 |
| Meningitis aseptic | 1 | 0 |
| Myelitis | 1 | 0 |
| <i>Corynebacteria infections</i> | | |
| Corynebacterium infection | 1 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 1 | 0 |
| Labyrinthitis | 1 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Infectious mononucleosis | 3 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 1 | 0 |
| <i>Flaviviral infections</i> | | |
| Yellow fever vaccine-associated viscerotropic disease | 1 | 0 |
| <i>Hepatitis virus infections</i> | | |
| Hepatitis A | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Herpes simplex | 1 | 0 |
| Herpes zoster | 1 | 0 |
| <i>Infections NEC</i> | | |
| Infection | 3 | 0 |
| Injection site abscess | 1 | 0 |
| Respiratory tract infection | 1 | 0 |
| Vestibulitis | 1 | 0 |
| <i>Influenza viral infections</i> | | |
| Influenza | 8 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Bronchitis | 1 | 0 |
| Lower respiratory tract infection | 4 | 0 |
| <i>Mumps viral infections</i> | | |
| Mumps | 1 | 0 |
| <i>Muscle and soft tissue infections</i> | | |
| Soft tissue infection | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Neutropenic sepsis | 1 | 0 |
| Sepsis | 4 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Skin infection | 3 | 0 |
| <i>Staphylococcal infections</i> | | |
| Staphylococcal abscess | 1 | 0 |
| <i>Streptococcal infections</i> | | |

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|---|------------|----------|
| Infections | | |
| Infections cont'd | | |
| Pneumococcal sepsis | 1 | 1 |
| Streptococcal infection | 1 | 0 |
| Upper respiratory tract infections | | |
| Nasopharyngitis | 21 | 0 |
| Pharyngitis | 3 | 0 |
| Rhinitis | 2 | 0 |
| Sinusitis | 1 | 0 |
| Tonsillitis | 2 | 0 |
| Urinary tract infections | | |
| Urinary tract infection | 1 | 0 |
| Vascular infections | | |
| Lymphangitis | 1 | 0 |
| Viral infections NEC | | |
| Encephalitis viral | 1 | 0 |
| Meningitis viral | 1 | 0 |
| Post viral fatigue syndrome | 2 | 0 |
| Viral diarrhoea | 1 | 0 |
| Viral infection | 3 | 0 |
| Viral pericarditis | 1 | 0 |
| Infections SOC TOTAL | 103 | 1 |

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| Injuries | | |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 9 | 0 |
| Foetal exposure during pregnancy | 7 | 0 |
| Foetal exposure timing unspecified | 1 | 0 |
| Maternal exposure before pregnancy | 2 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Medication error | 2 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Epicondylitis | 1 | 0 |
| Muscle injury | 1 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 1 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Fall | 5 | 0 |
| Traumatic haematoma | 1 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Shunt malfunction | 1 | 0 |
| <i>Off label uses</i> | | |
| Off label use | 1 | 0 |
| <i>Overdoses NEC</i> | | |
| Overdose | 1 | 0 |
| <i>Poisoning and toxicity</i> | | |
| Toxicity to various agents | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Expired product administered | 3 | 0 |
| Extra dose administered | 3 | 0 |
| Product administered at inappropriate site | 1 | 0 |
| Product administered to patient of inappropriate age | 1 | 0 |
| Wrong product administered | 5 | 0 |
| <i>Product storage errors and issues in the product use system</i> | | |
| Product storage error | 1 | 0 |
| <i>Reproductive system and breast injuries</i> | | |
| Perineal injury | 1 | 0 |
| <i>Site specific injuries NEC</i> | | |
| Head injury | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 7 | 0 |
| Scratch | 1 | 0 |
| Injuries SOC TOTAL | 58 | 0 |

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| Investigations | | |
| <i>Blood gas and acid base analyses</i> | | |
| Oxygen consumption increased | 1 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose decreased | 5 | 0 |
| Blood glucose increased | 2 | 0 |
| <i>Cell marker analyses</i> | | |
| Carbohydrate antigen 19-9 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 abnormal | 1 | 0 |
| <i>Foetal and neonatal diagnostic procedures</i> | | |
| Foetal heart rate abnormal | 1 | 0 |
| Foetal monitoring abnormal | 1 | 0 |
| <i>Haematological analyses NEC</i> | | |
| Red blood cell sedimentation rate increased | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate decreased | 2 | 0 |
| Heart rate increased | 11 | 0 |
| Heart rate irregular | 2 | 0 |
| Pulse abnormal | 18 | 0 |
| Pulse absent | 1 | 0 |
| <i>Hepatobiliary function diagnostic procedures</i> | | |
| Alanine aminotransferase increased | 4 | 0 |
| Aspartate aminotransferase increased | 1 | 0 |
| Blood bilirubin increased | 3 | 0 |
| Liver function test abnormal | 4 | 0 |
| Liver function test increased | 1 | 0 |
| Transaminases increased | 1 | 0 |
| <i>Investigations NEC</i> | | |
| Quality of life decreased | 1 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood iron decreased | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature abnormal | 1 | 0 |
| Body temperature decreased | 1 | 0 |
| Body temperature fluctuation | 1 | 0 |
| Body temperature increased | 78 | 0 |
| General physical condition abnormal | 1 | 0 |
| Respiratory rate increased | 5 | 0 |
| Weight decreased | 3 | 0 |
| Weight increased | 1 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count increased | 1 | 0 |
| Platelet morphology abnormal | 1 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein increased | 3 | 0 |
| <i>Respiratory and pulmonary function diagnostic procedures</i> | | |
| Vital capacity decreased | 1 | 0 |
| <i>Urinalysis NEC</i> | | |
| Blood urine present | 3 | 0 |

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Report Run Date: 23-Nov-2022

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Investigations Investigations cont'd | | |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure abnormal | 1 | 0 |
| Blood pressure decreased | 5 | 0 |
| Blood pressure diastolic increased | 1 | 0 |
| Blood pressure increased | 5 | 0 |
| <i>Vitamin analyses</i> | | |
| Vitamin D decreased | 1 | 0 |
| <i>White blood cell analyses</i> | | |
| Lymphocyte count increased | 1 | 0 |
| Lymphocyte morphology abnormal | 2 | 0 |
| Neutrophil count abnormal | 2 | 0 |
| Neutrophil toxic granulation present | 1 | 0 |
| Investigations SOC TOTAL | 184 | 0 |

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Report Run Date: 23-Nov-2022

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Earliest Reaction Date: 24-Feb-2004

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 1 | 0 |
| Decreased appetite | 57 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Dairy intolerance | 1 | 0 |
| Food intolerance | 1 | 0 |
| Milk soy protein intolerance | 1 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 2 | 0 |
| Feeding disorder | 2 | 0 |
| <i>Hyperglycaemic conditions NEC</i> | | |
| Glucose tolerance impaired | 1 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Hypoglycaemia | 1 | 0 |
| <i>Mixed acid-base disorders</i> | | |
| Acidosis | 1 | 0 |
| Metabolic disorders SOC TOTAL | 68 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 3 | 0 |
| Arthropathy | 2 | 0 |
| <i>Bone disorders NEC</i> | | |
| Jaw disorder | 1 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 1 | 0 |
| Pain in jaw | 2 | 0 |
| Spinal pain | 2 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 1 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Connective tissue disorder | 1 | 0 |
| Morphoea | 1 | 0 |
| Myofascitis | 1 | 0 |
| Polymyalgia rheumatica | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Periarthritis | 2 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 79 | 0 |
| Joint effusion | 1 | 0 |
| Joint stiffness | 7 | 0 |
| Joint swelling | 6 | 0 |
| <i>Metabolic bone disorders</i> | | |
| Osteoporosis | 1 | 0 |
| <i>Muscle infections and inflammations</i> | | |
| Myositis | 1 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 92 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle atrophy | 1 | 0 |
| Muscle fatigue | 4 | 0 |
| Muscle spasms | 16 | 0 |
| Muscle swelling | 3 | 0 |
| Muscle twitching | 17 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 14 | 0 |
| Trismus | 5 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 27 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Growth retardation | 1 | 0 |
| Limb mass | 1 | 0 |
| Mastication disorder | 1 | 0 |
| Mobility decreased | 2 | 0 |
| Musculoskeletal stiffness | 44 | 0 |
| Posture abnormal | 2 | 0 |
| Weight bearing difficulty | 1 | 0 |
| <i>Musculoskeletal and connective tissue infections and inflammations NEC</i> | | |
| Dactylitis | 1 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 62 | 0 |
| Limb discomfort | 20 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Musculoskeletal chest pain | 1 | 0 |
| Musculoskeletal discomfort | 1 | 0 |
| Musculoskeletal pain | 4 | 0 |
| Neck pain | 32 | 0 |
| Pain in extremity | 184 | 0 |
| Rheumatic disorder | 1 | 0 |
| <i>Rheumatoid arthropathies</i> | | |
| Rheumatoid arthritis | 3 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Axillary mass | 4 | 0 |
| Groin pain | 1 | 0 |
| Neck mass | 1 | 0 |
| <i>Tendon disorders</i> | | |
| Tendonitis | 1 | 0 |
| Tenosynovitis | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 661 | 0 |

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Neoplasms | | |
| <i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i> | | |
| Adenocarcinoma pancreas | 1 | 0 |
| Neoplasms SOC TOTAL | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Acute polyneuropathies</i> | | |
| Guillain-Barre syndrome | 5 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Cerebral haemorrhage | 1 | 1 |
| <i>Cerebrovascular venous and sinus thrombosis</i> | | |
| Cerebral venous sinus thrombosis | 1 | 0 |
| <i>Chronic polyneuropathies</i> | | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 1 | 0 |
| Demyelinating polyneuropathy | 1 | 0 |
| <i>Coma states</i> | | |
| Coma | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Ataxia | 3 | 0 |
| Balance disorder | 5 | 0 |
| Cerebellar ataxia | 1 | 0 |
| Cerebellar syndrome | 1 | 0 |
| Coordination abnormal | 2 | 0 |
| Dysstasia | 2 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 2 | 0 |
| <i>Demyelinating disorders NEC</i> | | |
| Acute disseminated encephalomyelitis | 4 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Altered state of consciousness | 1 | 0 |
| Consciousness fluctuating | 1 | 0 |
| Depressed level of consciousness | 3 | 0 |
| Lethargy | 67 | 0 |
| Loss of consciousness | 35 | 0 |
| Somnolence | 53 | 0 |
| Syncope | 222 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Dyskinesia | 33 | 0 |
| Hypokinesia | 7 | 0 |
| Movement disorder | 1 | 0 |
| Psychomotor hyperactivity | 2 | 0 |
| <i>Dystonias</i> | | |
| Opisthotonus | 1 | 0 |
| <i>Encephalopathies NEC</i> | | |
| Encephalopathy | 1 | 0 |
| <i>Facial cranial nerve disorders</i> | | |
| Bell's palsy | 4 | 0 |
| Facial paralysis | 2 | 0 |
| Facial paresis | 1 | 0 |
| Facial spasm | 1 | 0 |
| <i>Generalised tonic-clonic seizures</i> | | |
| Generalised tonic-clonic seizure | 3 | 0 |
| <i>Headaches NEC</i> | | |
| Cluster headache | 1 | 0 |
| Headache | 524 | 0 |
| Tension headache | 3 | 0 |
| <i>Intellectual disabilities</i> | | |
| Intellectual disability | 1 | 0 |
| <i>Memory loss (excl dementia)</i> | | |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Amnesia | 4 | 0 |
| Memory impairment | 1 | 0 |
| Mental impairment (excl dementia and memory loss) | | |
| Cognitive disorder | 2 | 0 |
| Disturbance in attention | 7 | 0 |
| Judgement impaired | 1 | 0 |
| Migraine headaches | | |
| Migraine | 10 | 0 |
| Migraine with aura | 1 | 0 |
| Multiple sclerosis acute and progressive | | |
| Multiple sclerosis | 1 | 0 |
| Muscle tone abnormal | | |
| Hypertonia | 1 | 0 |
| Hypotonia | 5 | 0 |
| Myelitis (incl infective) | | |
| Myelitis transverse | 1 | 0 |
| Narcolepsy and hypersomnia | | |
| Hypersomnia | 5 | 0 |
| Nervous system disorders NEC | | |
| Brain stem syndrome | 1 | 0 |
| Neurologic visual problems NEC | | |
| Tunnel vision | 2 | 0 |
| Neurological signs and symptoms NEC | | |
| Dizziness | 430 | 0 |
| Dizziness postural | 4 | 0 |
| Drooling | 1 | 0 |
| Head discomfort | 5 | 0 |
| Hyporesponsive to stimuli | 1 | 0 |
| Myoclonus | 4 | 0 |
| Neurological symptom | 1 | 0 |
| Presyncope | 34 | 0 |
| Unresponsive to stimuli | 20 | 0 |
| Neuromuscular disorders NEC | | |
| Hypotonic-hyporesponsive episode | 1 | 0 |
| Muscle spasticity | 1 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning sensation | 5 | 0 |
| Dysaesthesia | 1 | 0 |
| Formication | 1 | 0 |
| Hyperaesthesia | 8 | 0 |
| Hypoaesthesia | 52 | 0 |
| Paraesthesia | 78 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Diplegia | 2 | 0 |
| Hemiparesis | 2 | 0 |
| Monoparesis | 1 | 0 |
| Monoplegia | 1 | 0 |
| Paralysis | 3 | 0 |
| Quadriparesis | 1 | 0 |
| Peripheral neuropathies NEC | | |
| Neuropathy peripheral | 3 | 0 |
| Peripheral sensory neuropathy | 1 | 0 |
| Polyneuropathy | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| <i>Seizures and seizure disorders NEC</i> | | |
| Epilepsy | 5 | 0 |
| Febrile convulsion | 3 | 0 |
| Seizure | 32 | 0 |
| Seizure like phenomena | 3 | 0 |
| Tonic clonic movements | 3 | 0 |
| Tonic convulsion | 1 | 0 |
| <i>Sensory abnormalities NEC</i> | | |
| Ageusia | 1 | 0 |
| Dysgeusia | 3 | 0 |
| Electric shock sensation | 1 | 0 |
| Neuralgia | 2 | 0 |
| Sensory disturbance | 3 | 0 |
| Sensory loss | 6 | 0 |
| Taste disorder | 1 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Dysarthria | 10 | 0 |
| Incoherent | 1 | 0 |
| Speech disorder | 3 | 0 |
| <i>Spinal cord and nerve root disorders NEC</i> | | |
| Radiculitis brachial | 4 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Intention tremor | 1 | 0 |
| Tremor | 69 | 0 |
| <i>Trigeminal disorders</i> | | |
| Trigeminal neuralgia | 1 | 0 |
| Nervous system disorders SOC TOTAL | 1854 | 1 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Pregnancy conditions | | |
| <i>Abortion related conditions and complications</i> | | |
| Anembryonic gestation | 1 | 0 |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 12 | 0 |
| <i>Amniotic fluid and cavity disorders of pregnancy NEC</i> | | |
| Meconium in amniotic fluid | 1 | 0 |
| <i>Foetal complications NEC</i> | | |
| Foetal cardiac disorder | 1 | 0 |
| Foetal distress syndrome | 4 | 0 |
| Foetal hypokinesia | 1 | 0 |
| <i>Gestational age and weight conditions</i> | | |
| Premature baby | 1 | 0 |
| <i>Haemorrhagic complications of pregnancy</i> | | |
| Haemorrhage in pregnancy | 1 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Prolonged labour | 1 | 0 |
| <i>Maternal complications of delivery NEC</i> | | |
| Complication of delivery | 1 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Complication of pregnancy | 1 | 0 |
| Ectopic pregnancy | 1 | 0 |
| <i>Neonatal hepatobiliary disorders</i> | | |
| Jaundice neonatal | 1 | 0 |
| <i>Normal newborn status</i> | | |
| Normal newborn | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 28 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 3 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder | 7 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 7 | 0 |
| Anxiety | 15 | 0 |
| Nervousness | 3 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 3 | 0 |
| Indifference | 1 | 0 |
| Paranoia | 1 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 15 | 0 |
| Disorientation | 18 | 0 |
| <i>Deliria</i> | | |
| Delirium | 7 | 0 |
| <i>Dissociative states</i> | | |
| Dissociation | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 13 | 0 |
| <i>Dyssomnias</i> | | |
| Poor quality sleep | 2 | 0 |
| <i>Eating disorders NEC</i> | | |
| Eating disorder | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Emotional disorder | 4 | 0 |
| Emotional distress | 3 | 0 |
| Irritability | 3 | 0 |
| Mood altered | 1 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Fear | 1 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 11 | 0 |
| Hallucination, visual | 1 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 1 | 0 |
| <i>Learning disorders</i> | | |
| Learning disability | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Depressed mood | 1 | 0 |
| Tearfulness | 2 | 0 |
| <i>Mood disorders NEC</i> | | |
| Affective disorder | 1 | 0 |
| Listless | 3 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Panic attack | 2 | 0 |
| Panic reaction | 3 | 0 |
| <i>Parasomnias</i> | | |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Psychiatric disorders Psychiatric disorders cont'd | | |
| Nightmare | 1 | 0 |
| Personality disorders with dramatic behaviour (Cluster B) | | |
| Borderline personality disorder | 1 | 0 |
| Psychiatric elimination disorders | | |
| Enuresis | 2 | 0 |
| Psychotic disorder NEC | | |
| Acute psychosis | 1 | 0 |
| Psychotic disorder | 2 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 10 | 0 |
| Somatic symptom disorders | | |
| Conversion disorder | 1 | 0 |
| Somatic symptom disorder | 1 | 0 |
| Speech articulation and rhythm disturbances | | |
| Lack of spontaneous speech | 1 | 0 |
| Stereotypies and automatisms | | |
| Bruxism | 2 | 0 |
| Tic disorders | | |
| Tic | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 160 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Dysuria | 2 | 0 |
| Incontinence | 4 | 0 |
| Mixed incontinence | 1 | 0 |
| Pollakiuria | 1 | 0 |
| Urinary incontinence | 5 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Glomerulonephritis acute | 1 | 0 |
| Goodpasture's syndrome | 1 | 0 |
| <i>Nephritis NEC</i> | | |
| Nephritis | 1 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 1 | 0 |
| Renal failure | 1 | 0 |
| <i>Renal failure complications</i> | | |
| Azotaemia | 1 | 0 |
| <i>Renal obstructive disorders</i> | | |
| Hydronephrosis | 1 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 4 | 0 |
| Haematuria | 1 | 0 |
| Renal & urinary disorders SOC TOTAL | 25 | 0 |

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Reproductive & breast disorders | | |
| <i>Breast signs and symptoms</i> | | |
| Breast tenderness | 1 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Amenorrhoea | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Pelvic pain | 1 | 0 |
| <i>Scrotal disorders NEC</i> | | |
| Scrotal pain | 1 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |
| Testicular swelling | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 5 | 0 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Dyspnoea | 58 | 0 |
| Grunting | 1 | 0 |
| Hyperventilation | 8 | 0 |
| Hypopnoea | 3 | 0 |
| Respiration abnormal | 1 | 0 |
| Respiratory arrest | 2 | 0 |
| Tachypnoea | 1 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Fibrinous bronchitis | 1 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 8 | 0 |
| Bronchospasm | 1 | 0 |
| Obstructive airways disorder | 1 | 0 |
| Wheezing | 11 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Hypoxia | 1 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 19 | 0 |
| Haemoptysis | 1 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Stridor | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 3 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 6 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Sinus congestion | 1 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Lung consolidation | 1 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal hypoaesthesia | 2 | 0 |
| Pharyngeal paraesthesia | 1 | 0 |
| Pharyngeal swelling | 10 | 0 |
| <i>Pleural infections and inflammations</i> | | |
| Pleurisy | 1 | 0 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Painful respiration | 2 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 2 | 0 |
| Choking | 1 | 0 |
| Dry throat | 1 | 0 |
| Dysphonia | 4 | 0 |
| Oropharyngeal discomfort | 2 | 0 |
| Oropharyngeal pain | 57 | 0 |
| Rhinorrhoea | 4 | 0 |
| Throat irritation | 8 | 0 |
| Throat tightness | 13 | 0 |
| Respiratory disorders SOC TOTAL | 237 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 1 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 7 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 39 | 0 |
| Hyperhidrosis | 48 | 0 |
| Night sweats | 3 | 0 |
| <i>Bullous conditions</i> | | |
| Erythema multiforme | 3 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 5 | 0 |
| Macule | 1 | 0 |
| Pain of skin | 3 | 0 |
| Papule | 1 | 0 |
| Sensitive skin | 1 | 0 |
| Skin burning sensation | 1 | 0 |
| Skin discolouration | 14 | 0 |
| Skin discomfort | 1 | 0 |
| Skin induration | 1 | 0 |
| Skin lesion | 1 | 0 |
| Skin reaction | 2 | 0 |
| Skin swelling | 1 | 0 |
| Skin warm | 16 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 2 | 0 |
| Dermatitis allergic | 6 | 0 |
| Eczema | 2 | 0 |
| Skin irritation | 2 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 95 | 0 |
| <i>Exfoliative conditions</i> | | |
| Exfoliative rash | 1 | 0 |
| Skin exfoliation | 2 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Pityriasis rosea | 2 | 0 |
| <i>Photosensitivity and photodermatosis conditions</i> | | |
| Photosensitivity reaction | 3 | 0 |
| <i>Pigmentation changes NEC</i> | | |
| Pigmentation disorder | 1 | 0 |
| <i>Pruritus NEC</i> | | |
| Pruritus | 54 | 0 |
| <i>Purpura and related conditions</i> | | |
| Ecchymosis | 1 | 0 |
| Henoch-Schonlein purpura | 2 | 0 |
| Petechiae | 2 | 0 |
| Purpura | 3 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Rash | 130 | 0 |
| Rash erythematous | 9 | 0 |
| Rash macular | 23 | 0 |
| Rash maculo-papular | 2 | 0 |
| Rash papular | 8 | 0 |

Case Series Drug Analysis Print

Name: Revaxis Vaccine Analysis Print

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 24-Feb-2004

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Rash pruritic | 12 | 0 |
| Rash rubelliform | 1 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Subcutaneous emphysema | 2 | 0 |
| Skin hyperplasias and hypertrophies | | |
| Skin hypertrophy | 1 | 0 |
| Skin vasculitides | | |
| Cutaneous vasculitis | 1 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 6 | 0 |
| Urticarias | | |
| Urticaria | 59 | 0 |
| Urticaria chronic | 2 | 0 |
| Skin disorders SOC TOTAL | 583 | 0 |

Case Series Drug Analysis Print

Name: Revaxis Vaccine Analysis Print

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 24-Feb-2004

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|----------|----------|
| Social circumstances | | |
| <i>Disability issues</i> | | |
| Impaired work ability | 2 | 0 |
| Loss of personal independence in daily activities | 1 | 0 |
| Social circumstances SOC TOTAL | 3 | 0 |

Case Series Drug Analysis Print

Name: Revaxis Vaccine Analysis Print

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 24-Feb-2004

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|----------|----------|
| Surgical & medical procedures | | |
| <i>Induced abortions</i> | | |
| Abortion induced | 4 | 0 |
| <i>Obstetric therapeutic procedures</i> | | |
| Caesarean section | 3 | 0 |
| Vacuum extractor delivery | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 8 | 0 |

Case Series Drug Analysis Print

Name: Revaxis Vaccine Analysis Print

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 24-Feb-2004

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Vascular disorders | | |
| <i>Arterial infections and inflammations</i> | | |
| Giant cell arteritis | 1 | 0 |
| <i>Blood pressure disorders NEC</i> | | |
| Labile blood pressure | 1 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 6 | 0 |
| Shock | 3 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haematoma | 1 | 0 |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 1 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Thrombosis | 1 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | |
| Thrombophlebitis | 2 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 6 | 0 |
| Flushing | 21 | 0 |
| Hot flush | 4 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 15 | 0 |
| Poor peripheral circulation | 1 | 0 |
| Raynaud's phenomenon | 2 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 109 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 3 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Hypotension | 22 | 0 |
| Orthostatic hypotension | 1 | 0 |
| Vascular disorders SOC TOTAL | 200 | 0 |
| TOTAL REACTIONS FOR DRUG | 7628 | 5 |
| TOTAL REPORTS | 2288 | |
| TOTAL FATAL OUTCOME REPORTS | | 5 |