

Case Series Drug Analysis Print

Name: Pediacel FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 18-Dec-2000
MedDRA Version: MedDRA 24.0

Pediacel FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the Pediacel Vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Haematological disorders</i>		
Mastocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphoid tissue hyperplasia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiovascular disorder	2	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	9	0
Tachycardia	4	0
<i>Supraventricular arrhythmias</i>		
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	4	1
Cardiac disorders SOC TOTAL	20	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
<i>Neurological disorders congenital NEC</i>		
Congenital nystagmus	1	0
<i>Persistent foetal circulation disorders</i>		
Patent ductus arteriosus	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
Ear disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Cataract conditions</i>		
Cataract	1	0
<i>Eyelid movement disorders</i>		
Eyelid ptosis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	11	0
<i>Pupil disorders</i>		
Mydriasis	2	0
Pupil fixed	1	0
Pupils unequal	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	4	0
Eye disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Colitis (excl infective)</i>		
Necrotising colitis	2	1
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	48	0
Diarrhoea haemorrhagic	1	0
Diarrhoea neonatal	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	3	0
Abdominal pain upper	2	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	4	0
Intestinal dilatation	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Necrotising enterocolitis neonatal	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	5	0
Gastrointestinal wall thickening	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
<i>Nausea and vomiting symptoms</i>		
Infantile spitting up	1	0
Infantile vomiting	1	0
Nausea	2	0
Regurgitation	1	0
Retching	1	0
Vomiting	68	0
Vomiting projectile	3	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	4	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	3	0
Mouth swelling	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	7	0
Tongue oedema	1	0
Gastrointestinal disorders SOC TOTAL	180	1

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Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Asthenic conditions</i>		
Decreased activity	1	0
Fatigue	3	0
Malaise	27	0
<i>Death and sudden death</i>		
Death	3	3
Sudden death	1	1
Sudden infant death syndrome	3	3
<i>Febrile disorders</i>		
Pyrexia	137	0
<i>Feelings and sensations NEC</i>		
Chills	2	0
Feeling abnormal	4	0
Feeling cold	2	0
Feeling drunk	1	0
Feeling hot	38	0
Feeling jittery	1	0
<i>Gait disturbances</i>		
Gait disturbance	4	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crepitations	1	0
Crying	152	0
Developmental delay	1	0
Foaming at mouth	2	0
Glassy eyes	2	0
High-pitched crying	20	0
Illness	2	0
Induration	1	0
Influenza like illness	1	0
Local reaction	45	0
Peripheral swelling	102	0
Pneumatosis	1	0
Screaming	67	0
Secretion discharge	2	0
Swelling	60	0
Swelling face	8	0
<i>Implant and catheter site reactions</i>		
Implant site warmth	1	0
<i>Inflammations</i>		
Inflammation	29	0
<i>Injection site reactions</i>		
Injection site atrophy	1	0
Injection site bruising	2	0
Injection site discolouration	5	0
Injection site erythema	74	0
Injection site haemorrhage	1	0
Injection site induration	4	0
Injection site inflammation	18	0
Injection site irritation	1	0
Injection site mass	14	0

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General disorders General disorders cont'd		
Injection site pain	14	0
Injection site pruritus	1	0
Injection site rash	6	0
Injection site reaction	32	0
Injection site swelling	64	0
Injection site urticaria	2	0
Injection site vesicles	3	0
Injection site warmth	8	0
Mass conditions NEC		
Mass	4	0
Oedema NEC		
Localised oedema	2	0
Oedema peripheral	10	0
Pain and discomfort NEC		
Chest discomfort	1	0
Discomfort	6	0
Pain	17	0
Tenderness	5	0
Therapeutic and nontherapeutic responses		
Immediate post-injection reaction	1	0
Vaccination failure	5	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Vaccination site erythema	6	0
Vaccination site granuloma	1	0
Vaccination site haemorrhage	1	0
Vaccination site induration	1	0
Vaccination site mass	1	0
Vaccination site pain	1	0
Vaccination site plaque	1	0
Vaccination site rash	1	0
Vaccination site swelling	7	0
Vaccination site warmth	3	0
General disorders SOC TOTAL	1052	7

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	15	0
Serum sickness-like reaction	1	0
Type III immune complex mediated reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
Milk allergy	1	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	23	0
Anaphylactoid reaction	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immunisation reaction	3	0
Immune system disorders SOC TOTAL	48	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	13	0
Pneumonia bacterial	1	0
Vaccination site cellulitis	5	0
<i>Bordetella infections</i>		
Pertussis	3	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis	2	0
Meningitis aseptic	2	0
<i>Ear infections</i>		
Ear infection	2	0
<i>Haemophilus infections</i>		
Haemophilus infection	1	1
Meningitis haemophilus	1	0
Pneumonia haemophilus	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	1	0
Oral herpes	1	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	2	0
Injection site abscess	4	0
Injection site infection	4	0
Vaccination site abscess	3	0
<i>Lower respiratory tract and lung infections</i>		
Pneumonia	5	1
<i>Neisseria infections</i>		
Meningococcal infection	2	0
Meningococcal sepsis	1	0
<i>Salmonella infections</i>		
Salmonellosis	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	3	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
Rash pustular	1	0
<i>Streptococcal infections</i>		
Pneumococcal infection	2	0
Pneumococcal sepsis	2	1
<i>Upper respiratory tract infections</i>		
Croup infectious	1	0
Epiglottitis	2	0
Nasopharyngitis	2	0
Tonsillitis	3	0
Tracheitis	1	0
Upper respiratory tract infection	1	0
<i>Viral infections NEC</i>		
Bronchiolitis	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Conjunctivitis viral	1	0
Viral infection	4	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	86	3

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Subdural haemorrhage	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	2	0
Foetal exposure during pregnancy	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
<i>Non-site specific injuries NEC</i>		
Wound secretion	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	3	0
<i>Peripheral nerve injuries</i>		
Injury to brachial plexus due to birth trauma	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Inappropriate schedule of product administration	4	0
Incorrect dose administered	1	0
Product administered to patient of inappropriate age	1	0
Product administration error	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>Skin injuries NEC</i>		
Contusion	11	0
Scratch	1	0
<i>Vaccination related complications</i>		
Vaccination complication	4	0
Injuries SOC TOTAL	43	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	9	0
<i>Coagulation and bleeding analyses</i>		
Coagulation test abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Heart rate increased	4	0
<i>Immunology analyses NEC</i>		
Tryptase increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
Body temperature increased	19	0
Respiratory rate decreased	2	0
<i>Platelet analyses</i>		
Platelet count increased	2	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	5	0
<i>Renal function analyses</i>		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray abnormal	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
White blood cell count increased	3	0
Investigations SOC TOTAL	54	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	16	0
Hypophagia	2	0
Increased appetite	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	2	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Failure to thrive	1	0
Feeding disorder	11	0
Food aversion	2	0
Poor feeding infant	14	0
Weight gain poor	3	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	56	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Polyarthritis	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
<i>Joint related signs and symptoms</i>		
Joint swelling	4	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle swelling	1	0
Muscle twitching	2	0
<i>Muscle tone abnormalities</i>		
Floppy infant	13	0
Muscle rigidity	8	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	5	0
Toe walking	1	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Pain in extremity	10	0
Muscle & tissue disorders SOC TOTAL	50	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Astrocytoma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Hyperreflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Intraventricular haemorrhage	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
Coordination abnormal	1	0
Hand-eye coordination impaired	1	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Dyspraxia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	3	0
Lethargy	13	0
Loss of consciousness	9	0
Sedation	1	0
Somnolence	40	0
Syncope	11	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	11	0
Hypokinesia	2	0
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	4	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	43	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	6	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	2	0
Dizziness	1	0
Exaggerated startle response	1	0
Fontanelle bulging	1	0
Grimacing	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Unresponsive to stimuli	31	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	10	0
Paraesthesias and dysaesthesias		
Hyperaesthesia	1	0
Seizures and seizure disorders NEC		
Epilepsy	3	0
Febrile convulsion	6	0
Infantile spasms	2	0
Partial seizures	1	0
Seizure	43	0
Seizure cluster	2	0
Seizure like phenomena	1	0
Status epilepticus	1	0
Sensory abnormalities NEC		
Restless legs syndrome	1	0
Sensory disturbance	1	0
Speech and language abnormalities		
Speech disorder	1	0
Structural brain disorders NEC		
Brain injury	2	1
Tremor (excl congenital)		
Tremor	6	0
Nervous system disorders SOC TOTAL	286	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
Premature separation of placenta	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	3	0
<i>Normal newborn status</i>		
Normal newborn	1	0
Pregnancy conditions SOC TOTAL	7	0

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Reaction Name	Total	Fatal
<i>Product label issues</i>		
Product lot number issue	2	0
null SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	6	0
Breath holding	5	0
Staring	7	0
<i>Anxiety symptoms</i>		
Agitation	5	0
Anxiety	3	0
Nervousness	2	0
Stress	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Disturbance in social behaviour	1	0
Personality change	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Eating disorders NEC</i>		
Eating disorder	3	0
Selective eating disorder	3	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	11	0
Emotional poverty	1	0
Irritability	57	0
Mood altered	5	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
Social fear	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	10	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Mood disorders NEC</i>		
Listless	5	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Panic attacks and disorders</i>		
Panic reaction	1	0
<i>Personality disorders with anxious behaviour (Cluster C)</i>		
Dependent personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	5	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	9	0
<i>Speech articulation and rhythm disturbances</i>		
Lack of spontaneous speech	1	0
<i>Tic disorders</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Tic	1	0
Psychiatric disorders SOC TOTAL	157	0

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Report Run Date: 07-Oct-2021

Data Lock Date: 30-Sep-2021 18:30:04

Earliest Reaction Date: 18-Dec-2000

MedDRA Version: MedDRA 24.0

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

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive tract signs and symptoms NEC</i>		
Oedema genital	1	0
Reproductive & breast disorders SOC TOTAL	1	0

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Report Run Date: 07-Oct-2021
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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	17	0
Apnoeic attack	4	0
Dyspnoea	19	0
Grunting	2	0
Hypopnoea	6	0
Irregular breathing	1	0
Respiratory arrest	11	1
Respiratory distress	3	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	8	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	1
<i>Coughing and associated symptoms</i>		
Cough	13	0
Productive cough	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Neonatal hypoxic conditions</i>		
Infantile apnoea	2	0
<i>Newborn respiratory disorders NEC</i>		
Respiratory disorder neonatal	1	0
Transient tachypnoea of the newborn	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	7	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	4	0
Dysphonia	2	0
Oropharyngeal pain	1	0
Rhinorrhoea	3	0
Sneezing	1	0
Respiratory disorders SOC TOTAL	113	2

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	8	0
Hyperhidrosis	7	0
<i>Bullous conditions</i>		
Blister	11	0
Erythema multiforme	5	0
Pemphigoid	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	5	0
Macule	1	0
Pain of skin	2	0
Papule	1	0
Scab	1	0
Skin burning sensation	1	0
Skin discolouration	21	0
Skin discomfort	1	0
Skin disorder	2	0
Skin induration	1	0
Skin lesion	3	0
Skin odour abnormal	1	0
Skin reaction	14	0
Skin sensitisation	1	0
Skin swelling	1	0
Skin tightness	2	0
Skin warm	11	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	4	0
Dermatitis atopic	1	0
Dermatitis diaper	2	0
Eczema	7	0
Eczema infantile	1	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	214	0
<i>Exfoliative conditions</i>		
Exfoliative rash	1	0
Skin exfoliation	1	0
<i>Pigmentation changes NEC</i>		
Post inflammatory pigmentation change	1	0
<i>Pruritus NEC</i>		
Pruritus	7	0
<i>Purpura and related conditions</i>		
Petechiae	33	0
Purpura	18	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	117	0
Rash erythematous	15	0
Rash macular	47	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash maculo-papular	10	0
Rash papular	7	0
Rash pruritic	3	0
Skin dystrophies		
Hypertrophic scar	1	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin vasculitides		
Vasculitic rash	2	0
Skin vasomotor conditions		
Livedo reticularis	9	0
Urticarias		
Urticaria	40	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	652	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	2	0
Social circumstances SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Middle ear therapeutic procedures</i>		
Ear tube insertion	1	0
<i>Obstetric therapeutic procedures</i>		
Vacuum extractor delivery	1	0
<i>Tonsillar therapeutic procedures</i>		
Adenoidectomy	1	0
Tonsillectomy	1	0
Surgical & medical procedures SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	4	0
Hypoperfusion	1	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary fragility	1	0
Hyperaemia	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	41	0
Flushing	7	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	86	0
Vascular disorders SOC TOTAL	154	0
TOTAL REACTIONS FOR DRUG	3012	15
TOTAL REPORTS	1152	
TOTAL FATAL OUTCOME REPORTS		15