

Case Series Drug Analysis Print
Name: FOI 21/590 Pediacel vaccine

Report Run Date: 29-Jun-2021
Data Lock Date: 08-Apr-2021 19:00:04
Earliest Reaction Date: 18-Dec-2000
MedDRA Version: MedDRA 23.1
FOI 21/590 Pediacel vaccine: All UK suspected, spontaneous adverse drug reactions reports associated with the Pediacel vaccine until 08/04/2021

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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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Reaction Name	Total	Fatal
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 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	1047	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
Kaposi's varicelliform eruption	1	0
Viral infection	4	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	87	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
Vaccination failure	5	0
Injuries SOC TOTAL	48	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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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	1	0
Renal & urinary disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: FOI 21/590 Pediacel vaccine

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 18-Dec-2000

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

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Report Run Date: 29-Jun-2021

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Earliest Reaction Date: 18-Dec-2000

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

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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

Case Series Drug Analysis Print

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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
<i>Skin dystrophies</i>		
Hypertrophic scar	1	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Skin vasculitides</i>		
Vasculitic rash	2	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	9	0
<i>Urticarias</i>		
Urticaria	40	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	652	0

Case Series Drug Analysis Print

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

Case Series Drug Analysis Print

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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	3013	15
TOTAL REPORTS	1152	
TOTAL FATAL OUTCOME REPORTS		15