

Case Series Drug Analysis Print

Name: FOI 24/033 PCV Vaccine Analysis Print

Report Run Date: 25-Jan-2024

Data Lock Date: 18-Jan-2024 17:24:12

Earliest Reaction Date: 21-Sep-2001

MedDRA Version: MedDRA 26.1

FOI 24/033 PCV All UK spontaneous suspected Adverse Drug Reaction
Vaccine Analysis Print: (ADR) reports associated with the PCV vaccine up to
and including 18/01/2024.

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Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	3	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	1	0
Anaemias haemolytic mechanical factor		
Haemolytic uraemic syndrome	5	0
Haematological disorders		
Mastocytosis	1	0
Haemolyses NEC		
Haemolysis	2	0
Leukocytoses NEC		
Leukocytosis	1	0
Lymphocytic infiltration	1	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	1	0
Lymphadenitis	1	0
Lymphadenopathy	5	0
Neutropenias		
Febrile neutropenia	1	0
Neutropenia	1	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	1	0
Thrombocytopenias		
Immune thrombocytopenia	2	0
Thrombocytopenia	5	0
Blood disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
Cardiovascular disorder	3	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
Pericardial haemorrhage	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	17	0
Bradycardia neonatal	1	0
Tachycardia	18	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	13	5
Cardio-respiratory arrest	4	1
Ventricular fibrillation	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	67	6

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
<i>Connective tissue disorders congenital</i>		
Hypermobility syndrome	2	0
<i>Gastric disorders congenital</i>		
Pyloric stenosis	1	0
<i>Neurological disorders congenital NEC</i>		
Congenital nystagmus	1	0
Congenital disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	4	0
Ear swelling	5	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	5	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	1	0
Ear disorders SOC TOTAL	20	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Eyelid movement disorders</i>		
Excessive eye blinking	4	0
Eyelid ptosis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Eyelid oedema	1	0
Swelling of eyelid	3	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye oedema	2	0
Eye swelling	16	0
Periorbital oedema	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	19	0
Gaze palsy	2	0
Strabismus	3	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	4	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	1	0
<i>Pupil disorders</i>		
Anisocoria	2	0
Miosis	2	0
Mydriasis	4	0
Pupil fixed	2	0
<i>Visual disorders NEC</i>		
Photopsia	1	0
Vision blurred	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	2	0
Cortical visual impairment	1	0
Visual impairment	5	0
Eye disorders SOC TOTAL	86	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>		
Colitis	2	0
Necrotising colitis	2	1
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	173	0
Diarrhoea haemorrhagic	2	0
Infantile diarrhoea	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	10	0
Faecaloma	1	0
Faeces discoloured	12	0
Faeces hard	1	0
Faeces pale	1	0
Faeces soft	2	0
Mucous stools	9	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	6	0
Flatulence	10	0
<i>Gastritis (excl infective)</i>		
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	13	0
Abdominal pain upper	19	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	13	0
Gastrooesophageal reflux disease	10	0
Intestinal dilatation	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Necrotising enterocolitis neonatal	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	12	0
Dysphagia	1	0
Gastrointestinal wall thickening	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	6	0
Irritable bowel syndrome	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intussusception	1	0
<i>Inguinal hernias</i>		
Inguinal hernia, obstructive	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile vomiting	4	0
Nausea	18	0
Regurgitation	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Vomiting	230	0
Vomiting projectile	17	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	13	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Lip blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Lip pain	1	0
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	12	0
Mouth swelling	2	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue disorders</i>		
Tongue disorder	1	0
Tongue geographic	1	0
<i>Tongue signs and symptoms</i>		
Protrusion tongue	2	0
Swollen tongue	3	0
Tongue blistering	1	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue movement disturbance	1	0
Gastrointestinal disorders SOC TOTAL	637	1

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site irritation	1	0
Application site papules	1	0
Application site rash	1	0
Application site swelling	2	0
<i>Asthenic conditions</i>		
Asthenia	17	0
Decreased activity	3	0
Fatigue	31	0
Malaise	97	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	2	0
<i>Death and sudden death</i>		
Brain death	1	0
Death	19	19
Sudden death	6	6
Sudden infant death syndrome	10	10
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	576	0
<i>Feelings and sensations NEC</i>		
Chills	18	0
Feeling abnormal	18	0
Feeling cold	4	0
Feeling drunk	1	0
Feeling hot	38	0
Feeling of body temperature change	1	0
Thirst	4	0
Thirst decreased	4	0
<i>Gait disturbances</i>		
Gait disturbance	12	0
Gait inability	11	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	11	0
Crepitations	1	0
Crying	198	0
Developmental delay	5	0
Developmental regression	1	0
Disease recurrence	1	0
Effusion	1	0
Foaming at mouth	1	0
General physical health deterioration	2	0
Glassy eyes	5	0
High-pitched crying	18	0
Illness	13	0
Induration	16	0
Influenza like illness	6	0
Irritability postvaccinal	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Local reaction	64	0
Moaning	2	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	115	0
Pneumatosis	1	0
Screaming	94	0
Secretion discharge	3	0
Swelling	79	0
Swelling face	22	0
Inflammations		
Inflammation	38	0
Injection site reactions		
Injected limb mobility decreased	1	0
Injection site bruising	7	0
Injection site cyst	1	0
Injection site discharge	1	0
Injection site discolouration	5	0
Injection site erosion	1	0
Injection site erythema	134	0
Injection site hypersensitivity	1	0
Injection site induration	14	0
Injection site inflammation	42	0
Injection site irritation	1	0
Injection site joint erythema	1	0
Injection site mass	33	0
Injection site movement impairment	1	0
Injection site oedema	3	0
Injection site pain	26	0
Injection site pruritus	2	0
Injection site rash	15	0
Injection site reaction	66	0
Injection site swelling	110	0
Injection site urticaria	5	0
Injection site vesicles	4	0
Injection site warmth	26	0
Mass conditions NEC		
Cyst	1	0
Mass	6	0
Oedema NEC		
Face oedema	2	0
Localised oedema	2	0
Oedema	4	0
Oedema peripheral	16	0
Pain and discomfort NEC		
Chest discomfort	3	0
Chest pain	2	0
Discomfort	14	0
Pain	63	0
Tenderness	19	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	10	0
Adverse reaction	1	0
Drug ineffective	212	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Immediate post-injection reaction	1	0
Therapeutic product ineffective	246	0
Vaccination failure	35	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	3	0
Vaccination site bruising	6	0
Vaccination site discomfort	1	0
Vaccination site erythema	48	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	1	0
Vaccination site induration	17	0
Vaccination site inflammation	9	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	28	0
Vaccination site movement impairment	3	0
Vaccination site pain	27	0
Vaccination site pruritus	2	0
Vaccination site rash	11	0
Vaccination site reaction	7	0
Vaccination site scab	1	0
Vaccination site swelling	39	0
Vaccination site urticaria	1	0
Vaccination site vesicles	2	0
Vaccination site warmth	14	0
General disorders SOC TOTAL	2947	35

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
Jaundice cholestatic	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
Hepatic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	1	0
Hypersensitivity	40	0
Multiple allergies	2	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>		
Allergy to vaccine	1	0
Drug hypersensitivity	1	0
Food allergy	3	0
Milk allergy	6	0
Reaction to excipient	2	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	32	1
Anaphylactic shock	2	0
Anaphylactoid reaction	1	0
<i>Immune and associated conditions NEC</i>		
Decreased immune responsiveness	1	0
Haemophagocytic lymphohistiocytosis	1	0
Immune system disorder	3	0
Immune-mediated adverse reaction	1	0
Sensitisation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	3	0
Immune system disorders SOC TOTAL	105	1

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	2	0
<i>Adenoviral infections</i>		
Adenovirus infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	4	0
Bacterial infection	1	0
Bacterial sepsis	4	0
Cellulitis	35	0
Injection site cellulitis	5	0
Meningitis bacterial	3	0
Pneumonia bacterial	1	0
Pyomyositis	1	0
Skin bacterial infection	3	0
Vaccination site cellulitis	6	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Bordetella infections</i>		
Pertussis	2	0
<i>Candida infections</i>		
Candida infection	1	0
Oral candidiasis	3	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Brain empyema	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	8	1
Meningitis	15	1
Meningitis aseptic	7	0
Subdural abscess	1	0
<i>Coronavirus infections</i>		
COVID-19	2	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Ear infections</i>		
Ear infection	10	0
Mastoiditis	4	0
Otitis media	3	0
Otitis media acute	1	0
Otitis media chronic	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
Meningitis enteroviral	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	7	0
Eye infection	1	0
<i>Haemophilus infections</i>		

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Infections		
Infections cont'd		
Haemophilus bacteraemia	1	0
Haemophilus sepsis	1	0
<i>Herpes viral infections</i>		
Herpes simplex	1	0
Herpes virus infection	1	0
Herpes zoster	1	0
Human herpesvirus 6 infection	2	0
Oral herpes	1	0
Varicella	1	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	2	0
Abscess limb	1	0
Empyema	64	0
Febrile infection	1	0
Infection	9	0
Injection site abscess	3	0
Injection site infection	3	0
Localised infection	2	0
Vaccination site abscess	5	0
Vaccination site infection	3	0
<i>Influenza viral infections</i>		
Influenza	5	0
Pneumonia influenzal	1	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	1	0
Bronchitis	4	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	26	0
Pneumonia	65	1
Pneumonia necrotising	1	0
<i>Mumps viral infections</i>		
Mumps	2	0
<i>Muscle and soft tissue infections</i>		
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Meningococcal infection	2	0
Meningococcal sepsis	1	0
<i>Parainfluenzae viral infections</i>		
Parainfluenzae virus infection	1	0
<i>Respiratory syncytial viral infections</i>		
Respiratory syncytial virus bronchiolitis	4	0
Respiratory syncytial virus infection	2	0
<i>Rhinoviral infections</i>		
Rhinovirus infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubella viral infections</i>		
Rubella	1	0
<i>Rubeola viral infections</i>		
Measles	2	0
<i>Salmonella infections</i>		
Salmonellosis	1	0

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Infections		
Infections cont'd		
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	23	0
Sepsis	38	0
Septic shock	1	0
Urosepsis	1	1
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
Skin infection	3	0
<i>Staphylococcal infections</i>		
Staphylococcal infection	1	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	51	2
Pharyngitis streptococcal	1	0
Pneumococcal bacteraemia	22	0
Pneumococcal infection	343	11
Pneumococcal sepsis	42	2
Pneumonia pneumococcal	41	1
Pneumonia streptococcal	17	0
Septic arthritis streptococcal	1	0
Streptococcal bacteraemia	1	0
Streptococcal sepsis	2	0
Tonsillitis streptococcal	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	4	0
Epiglottitis	1	0
Nasopharyngitis	13	0
Pharyngitis	1	0
Rhinitis	8	0
Tonsillitis	7	0
Upper respiratory tract infection	11	0
<i>Urinary tract infections</i>		
Kidney infection	1	0
Urinary tract infection	3	0
<i>Viral infections NEC</i>		
Bronchiolitis	8	0
Gastroenteritis viral	1	0
Viral infection	5	0
Viral rash	1	0
Viral upper respiratory tract infection	3	0
Infections SOC TOTAL	1027	20

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Craniocerebral injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	14	0
Product use in unapproved indication	3	0
Wrong technique in product usage process	2	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
<i>Non-site specific injuries NEC</i>		
Injury	1	0
Wound secretion	2	0
<i>Product administration errors and issues</i>		
Booster dose missed	1	0
Extra dose administered	1	0
Inappropriate schedule of product administration	13	0
Incomplete course of vaccination	1	0
Incorrect dose administered	2	0
Incorrect route of product administration	2	0
Product administered at inappropriate site	2	0
Product administered to patient of inappropriate age	7	0
Product administration error	4	0
Wrong product administered	1	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
Product prescribing issue	1	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	3	0
<i>Skin injuries NEC</i>		
Contusion	17	0
Scar	1	0
Scratch	1	0
Skin injury	1	0
Skin laceration	1	0
<i>Vaccination related complications</i>		
Immunisation reaction	5	0
Post vaccination syndrome	1	0
Vaccination complication	1	0
Injuries SOC TOTAL	95	0

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Investigations		
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Streptococcus test positive	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	20	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose fluctuation	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Central nervous system histopathology procedures</i>		
Biopsy brain abnormal	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF white blood cell count increased	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	2	0
<i>Coagulation and bleeding analyses</i>		
Coagulation test abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	3	0
Heart rate decreased	2	0
Heart rate increased	13	0
Pulse abnormal	1	0
<i>Immunology analyses NEC</i>		
Antibody test abnormal	2	0
Antibody test negative	2	0
Tryptase increased	1	0
<i>Metabolism tests NEC</i>		
Blood ketone body increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood magnesium decreased	1	0
Blood sodium decreased	2	0
<i>Ophthalmic function diagnostic procedures</i>		
Intraocular pressure increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature abnormal	4	0
Body temperature decreased	3	0
Body temperature fluctuation	3	0
Body temperature increased	66	0
Breath sounds abnormal	3	0
Respiratory rate decreased	1	0
Respiratory rate increased	3	0
Weight decreased	3	0
<i>Platelet analyses</i>		
Platelet count increased	3	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	17	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	3	0
<i>Renal function analyses</i>		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
White blood cells urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	4	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Capillary nail refill test abnormal	1	0
<i>Virus identification and serology</i>		
Coronavirus test positive	1	0
<i>White blood cell analyses</i>		
Eosinophil count increased	1	0
Lymphocyte count increased	1	0
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
White blood cell count increased	5	0
Investigations SOC TOTAL	187	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	101	0
Food refusal	2	0
Hypophagia	6	0
Increased appetite	1	0
<i>Cell metabolism disorders NEC</i>		
Mitochondrial cytopathy	1	0
<i>Chloride imbalance</i>		
Hyperchloraemia	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	3	0
Food intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Failure to thrive	1	0
Feeding disorder	8	0
Food aversion	4	0
Poor feeding infant	53	0
Weight gain poor	4	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	3	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	2	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	2	0
<i>Total fluid volume decreased</i>		
Dehydration	6	0
Metabolic disorders SOC TOTAL	209	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Polyarthritis	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	21	0
Joint effusion	1	0
Joint range of motion decreased	1	0
Joint swelling	6	0
Joint warmth	1	0
<i>Muscle pains</i>		
Myalgia	14	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle spasms	4	0
Muscle tightness	1	0
Muscle twitching	9	0
<i>Muscle tone abnormalities</i>		
Floppy infant	32	0
Muscle rigidity	7	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	4	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Musculoskeletal stiffness	21	0
Posture abnormal	2	0
Toe walking	1	0
Weight bearing difficulty	11	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Limb discomfort	6	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Neck pain	2	0
Pain in extremity	73	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	228	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	2	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Astrocytoma	1	0
<i>Rhabdomyosarcomas</i>		
Rhabdomyosarcoma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
Neoplasms SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	10	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	1	0
Intraventricular haemorrhage	1	0
Ruptured cerebral aneurysm	1	0
<i>Central nervous system vascular disorders NEC</i>		
Brain hypoxia	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous thrombosis	1	0
Superior sagittal sinus thrombosis	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	7	0
Coordination abnormal	1	0
Developmental coordination disorder	1	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	4	0
Dyspraxia	2	0
Sensory processing disorder	3	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	6	0
Lethargy	61	0
Loss of consciousness	17	0
Sedation	1	0
Somnolence	83	0
Syncope	16	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	26	0
Fine motor delay	1	0
Hypokinesia	3	0
Motor dysfunction	1	0
Movement disorder	3	0
Psychomotor hyperactivity	3	0
<i>Dystonias</i>		
Dystonia	1	0
Opisthotonus	3	0
<i>Encephalopathies NEC</i>		
Hypoxic-ischaemic encephalopathy	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	16	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	24	0
Tension headache	2	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	2	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Intellectual disabilities</i>		
Intellectual disability	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	3	0
<i>Migraine headaches</i>		
Migraine	1	0
Migraine with aura	1	0
<i>Muscle tone abnormal</i>		
Hypertonia	1	0
Hypotonia	67	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	11	0
<i>Nervous system disorders NEC</i>		
Brain stem syndrome	1	0
Nervous system disorder	5	0
Neurodegenerative disorder	1	0
Subdural effusion	3	0
<i>Neurological signs and symptoms NEC</i>		
Cerebrospinal fluid leakage	1	0
Dizziness	10	0
Dizziness exertional	1	0
Dizziness postural	1	0
Drooling	2	0
Exaggerated startle response	2	0
Fontanelle bulging	6	0
Grimacing	1	0
Hyporesponsive to stimuli	5	0
Inability to crawl	1	0
Infant irritability	3	0
Meningism	1	0
Myoclonus	1	0
Neurological decompensation	1	0
Neurological symptom	1	0
Pleocytosis	3	0
Presyncope	4	0
Unresponsive to stimuli	68	0
<i>Neuromuscular disorders NEC</i>		
Hypotonic-hypo-responsive episode	10	0
Muscle spasticity	1	0
Neuromyopathy	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	2	0
Hyperaesthesia	2	0
Hypoaesthesia	3	0
Paraesthesia	3	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Monoplegia	2	0
Paralysis	2	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	10	0
Epileptic encephalopathy	1	0
Febrile convulsion	49	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Infantile spasms	1	0
Partial seizures	9	0
Seizure	83	0
Seizure anoxic	1	0
Seizure cluster	2	0
Seizure like phenomena	1	0
Status epilepticus	4	0
<i>Sensory abnormalities NEC</i>		
Neuralgia	1	0
Restless legs syndrome	1	0
Sensory disturbance	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	3	0
Speech disorder developmental	3	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
<i>Tremor (excl congenital)</i>		
Tremor	25	0
Nervous system disorders SOC TOTAL	744	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	4	0
Pregnancy conditions SOC TOTAL	5	0

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Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Needle issue	2	0
<i>Product quality issues NEC</i>		
Product quality issue	4	0
null SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	23	0
Behaviour disorder	1	0
Breath holding	11	0
Regressive behaviour	1	0
Staring	10	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
<i>Affect alterations NEC</i>		
Flat affect	1	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	9	0
Anxiety	4	0
Stress	1	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	4	0
Disturbance in social behaviour	1	0
Personality change	4	0
Social avoidant behaviour	1	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
Disorientation	3	0
<i>Decreased physical activity levels</i>		
Catatonia	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	1	0
Insomnia	27	0
Middle insomnia	3	0
<i>Dyssomnias</i>		
Poor quality sleep	7	0
<i>Eating disorders NEC</i>		
Eating disorder	3	0
Selective eating disorder	5	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	30	0
Emotional poverty	1	0
Irritability	162	0
Mood altered	7	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear of eating	1	0
Social fear	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	5	0
Hallucination, auditory	1	0
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	31	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Mental disorders NEC</i>		
Mental disorder	3	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	5	0
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	9	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Parasomnias</i>		
Sleep terror	4	0
<i>Personality disorders with anxious behaviour (Cluster C)</i>		
Dependent personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	19	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	4	0
<i>Sleep disorders NEC</i>		
Sleep disorder	18	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
<i>Speech articulation and rhythm disturbances</i>		
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Head banging	3	0
<i>Suicidal and self-injurious behaviour</i>		
Self-injurious ideation	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	441	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Micturition urgency	1	0
Urinary retention	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	3	0
Anuria	1	0
Oliguria	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Urine abnormality	1	0
Renal & urinary disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital blister	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Genital swelling	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	36	0
Apnoeic attack	7	0
Dyspnoea	56	0
Grunting	5	0
Hyperventilation	1	0
Hypopnoea	9	0
Hypoventilation	2	0
Irregular breathing	1	0
Respiration abnormal	2	0
Respiratory arrest	19	1
Respiratory distress	11	0
Tachypnoea	8	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Wheezing	26	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hypoxia	3	1
Respiratory acidosis	1	0
<i>Coughing and associated symptoms</i>		
Cough	44	0
Haemoptysis	1	0
Productive cough	6	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	5	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pleuritic pain	1	0
Pulmonary haemorrhage	3	1
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	5	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Neonatal hypoxic conditions</i>		
Infantile apnoea	5	0
Neonatal hypoxia	3	0
<i>Parenchymal lung disorders NEC</i>		
Lung consolidation	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	7	0
Pharyngeal inflammation	1	0
Pharyngeal swelling	2	0
Pharyngeal ulceration	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	16	0
Pneumothorax	3	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	1	0
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	2	1
<i>Respiratory signs and symptoms NEC</i>		
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	1
Respiratory disorder	6	0
Respiratory tract oedema	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	5	0
Dysphonia	3	0
Nasal discomfort	1	0
Nasal obstruction	1	0
Oropharyngeal pain	13	0
Rhinorrhoea	18	0
Sneezing	1	0
Throat irritation	1	0
Respiratory disorders SOC TOTAL	364	6

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Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	6	0
Apocrine and eccrine gland disorders		
Cold sweat	11	0
Hyperhidrosis	17	0
Miliaria	1	0
Bullous conditions		
Blister	17	0
Dermatitis bullous	1	0
Erythema multiforme	9	0
Pemphigoid	3	0
Stevens-Johnson syndrome	1	0
Dermal and epidermal conditions NEC		
Dry skin	8	0
Macule	2	0
Pain of skin	5	0
Papule	8	0
Scab	3	0
Skin burning sensation	3	0
Skin discolouration	37	0
Skin discomfort	1	0
Skin disorder	3	0
Skin induration	3	0
Skin lesion	7	0
Skin odour abnormal	1	0
Skin plaque	1	0
Skin reaction	12	0
Skin tightness	4	0
Skin warm	30	0
Skin weeping	1	0
Yellow skin	1	0
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	21	0
Dermatitis atopic	2	0
Dermatitis diaper	7	0
Eczema	21	0
Eczema infantile	1	0
Eczema weeping	1	0
Skin irritation	1	0
Dermatitis ascribed to specific agent		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Erythemas		
Erythema	293	0
Exfoliative conditions		
Skin exfoliation	3	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Pruritus NEC		
Pruritus	25	0
Purpura and related conditions		
Ecchymosis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Henoch-Schonlein purpura	2	0
Petechiae	36	0
Purpura	21	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	289	0
Rash erythematous	45	0
Rash macular	75	0
Rash maculo-papular	16	0
Rash morbilliform	15	0
Rash papular	26	0
Rash pruritic	8	0
Rash rubelliform	2	0
Rash vesicular	4	0
<i>Skin and subcutaneous conditions NEC</i>		
Cellulite	1	0
Skin mass	6	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	24	0
<i>Urticarias</i>		
Urticaria	119	0
Urticaria pigmentosa	1	0
Urticaria pressure	1	0
Skin disorders SOC TOTAL	1267	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	3	0
Social circumstances SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Inner ear therapeutic procedures</i>		
Cochlea implant	1	0
<i>Therapeutic procedures NEC</i>		
Medical device removal	1	0
Surgical & medical procedures SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	1	0
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	1
<i>Circulatory collapse and shock</i>		
Circulatory collapse	7	0
Hypoperfusion	1	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Venous thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Fibromuscular dysplasia	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary fragility	1	0
Superficial vein prominence	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	38	0
Flushing	9	0
Hot flush	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	9	0
Poor peripheral circulation	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	124	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Vascular disorders SOC TOTAL	208	1
TOTAL REACTIONS FOR DRUG	8711	70
TOTAL REPORTS	3045	
TOTAL FATAL OUTCOME REPORTS		70