

Case Series Drug Analysis Print

Name: DTaP IPV HiB Vaccine

Report Run Date: 27-Oct-2022

Data Lock Date: 26-Oct-2022 18:30:05

Earliest Reaction Date: 18-Dec-2000

MedDRA Version: MedDRA 25.0

DTaP IPV HiB Vaccine: UK spontaneous ADRs received up to 26/10/2022

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Haematological disorders</i>		
Mastocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	3	0
Lymphoid tissue hyperplasia	1	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	5	0
Thrombocytopenia	4	0
Blood disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiovascular disorder	3	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
Pericardial haemorrhage	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	11	0
Bradycardia neonatal	1	0
Tachycardia	10	0
<i>Supraventricular arrhythmias</i>		
Atrial flutter	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	8	3
Cardio-respiratory arrest	1	0
Cardiac disorders SOC TOTAL	40	3

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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>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acrodermatitis enteropathica	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	2	0
<i>Hearing losses</i>		
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	2	0
Ear disorders SOC TOTAL	5	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	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	3	0
Eye swelling	4	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	3	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	16	0
Strabismus	3	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	2	0
<i>Pupil disorders</i>		
Anisocoria	1	0
Mydriasis	3	0
Pupil fixed	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	1	0
<i>Visual disorders NEC</i>		
Vision blurred	3	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Cortical visual impairment	1	0
Visual impairment	5	0
Eye disorders SOC TOTAL	54	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	90	0
Diarrhoea haemorrhagic	1	0
Diarrhoea neonatal	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	5	0
Faeces discoloured	7	0
Faeces soft	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	4	0
Flatulence	5	0
<i>Gastritis (excl infective)</i>		
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	8	0
Abdominal pain upper	8	0
Abdominal tenderness	1	0
Gastrointestinal pain	1	0
Infantile colic	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	11	0
Gastrooesophageal reflux disease	9	0
Intestinal dilatation	2	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	3	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Necrotising enterocolitis neonatal	1	0
<i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i>		
Gastrointestinal necrosis	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Dysphagia	1	0
Gastrointestinal wall thickening	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	3	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intussusception	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile spitting up	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Infantile vomiting	7	0
Nausea	3	0
Regurgitation	2	0
Retching	1	0
Vomiting	130	0
Vomiting projectile	9	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	8	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0
Mouth swelling	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
<i>Tongue disorders</i>		
Tongue disorder	1	0
<i>Tongue signs and symptoms</i>		
Protrusion tongue	1	0
Swollen tongue	8	0
Tongue movement disturbance	1	0
Tongue oedema	1	0
Gastrointestinal disorders SOC TOTAL	373	1

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Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site irritation	1	0
<i>Asthenic conditions</i>		
Asthenia	2	0
Chronic fatigue syndrome	1	0
Decreased activity	2	0
Fatigue	10	0
Malaise	56	0
<i>Body temperature altered</i>		
Hypothermia	2	0
<i>Death and sudden death</i>		
Death	6	6
Sudden death	2	2
Sudden infant death syndrome	5	5
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
PFAPA syndrome	1	0
Pyrexia	302	0
<i>Feelings and sensations NEC</i>		
Chills	5	0
Feeling abnormal	9	0
Feeling cold	4	0
Feeling drunk	1	0
Feeling hot	55	0
Feeling jittery	1	0
<i>Gait disturbances</i>		
Gait disturbance	5	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	6	0
Crepitations	1	0
Crying	223	0
Developmental delay	2	0
Discharge	1	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Glassy eyes	4	0
High-pitched crying	29	0
Illness	5	0
Induration	4	0
Influenza like illness	2	0
Irritability postvaccinal	2	0
Local reaction	70	0
Moaning	4	0
Peripheral swelling	145	0
Pneumatosis	1	0
Screaming	92	0
Secretion discharge	3	0
Swelling	85	0
Swelling face	14	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Unevaluable event	1	0
Implant and catheter site reactions		
Implant site warmth	1	0
Inflammations		
Inflammation	38	0
Injection site reactions		
Injection site atrophy	1	0
Injection site bruising	5	0
Injection site discharge	1	0
Injection site discolouration	5	0
Injection site erythema	111	0
Injection site granuloma	1	0
Injection site haemorrhage	1	0
Injection site induration	5	0
Injection site inflammation	22	0
Injection site irritation	2	0
Injection site mass	23	0
Injection site necrosis	1	0
Injection site oedema	1	0
Injection site pain	21	0
Injection site pruritus	1	0
Injection site rash	7	0
Injection site reaction	43	0
Injection site swelling	103	0
Injection site urticaria	2	0
Injection site vesicles	4	0
Injection site warmth	17	0
Mass conditions NEC		
Mass	5	0
Oedema NEC		
Localised oedema	2	0
Oedema	2	0
Oedema peripheral	13	0
Pain and discomfort NEC		
Axillary pain	1	0
Chest discomfort	1	0
Discomfort	11	0
Pain	41	0
Tenderness	6	0
Therapeutic and nontherapeutic responses		
Adverse reaction	1	0
Immediate post-injection reaction	1	0
Vaccination failure	8	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	0
Vaccination site bruising	2	0
Vaccination site erythema	17	0
Vaccination site granuloma	2	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	1	0
Vaccination site induration	5	0
Vaccination site inflammation	1	0
Vaccination site irritation	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site mass	10	0
Vaccination site nodule	1	0
Vaccination site pain	5	0
Vaccination site plaque	1	0
Vaccination site pruritus	1	0
Vaccination site rash	4	0
Vaccination site reaction	1	0
Vaccination site scar	1	0
Vaccination site swelling	15	0
Vaccination site warmth	4	0
General disorders SOC TOTAL	1755	13

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	24	0
Multiple allergies	1	0
Serum sickness-like reaction	1	0
Type III immune complex mediated reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Food allergy	3	0
Milk allergy	2	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	30	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	2	0
Immunisation reaction	10	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	83	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Bacterial infection	1	0
Cellulitis	27	0
Injection site cellulitis	1	0
Pneumonia bacterial	1	0
Vaccination site cellulitis	7	0
<i>Bordetella infections</i>		
Pertussis	6	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	4	0
Meningitis	3	0
Meningitis aseptic	6	0
<i>Ear infections</i>		
Ear infection	3	0
Otitis media	1	0
<i>Haemophilus infections</i>		
Haemophilus infection	1	1
Meningitis haemophilus	2	0
Pneumonia haemophilus	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	1	0
Oral herpes	1	0
<i>Infections NEC</i>		
Abscess	3	0
Infection	3	0
Injection site abscess	7	0
Injection site infection	5	0
Localised infection	1	0
Vaccination site abscess	4	0
Vaccination site infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	1	0
Pneumonia	8	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	11	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	2	0
Rash pustular	1	0
Skin infection	2	0
<i>Streptococcal infections</i>		
Pneumococcal infection	2	0
Pneumococcal sepsis	2	1

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Upper respiratory tract infections</i>		
Croup infectious	1	0
Epiglottitis	2	0
Nasopharyngitis	6	0
Tonsillitis	3	0
Tracheitis	1	0
Upper respiratory tract infection	2	0
<i>Urinary tract infections</i>		
Kidney infection	1	0
Urinary tract infection	3	0
<i>Viral infections NEC</i>		
Bronchiolitis	3	0
Conjunctivitis viral	1	0
Viral infection	4	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	155	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
Maternal exposure during pregnancy	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	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	4	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
Extra dose administered	1	0
Inappropriate schedule of product administration	3	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Product administered to patient of inappropriate age	2	0
Product administration error	1	0
Wrong product administered	8	0
<i>Product preparation errors and issues</i>		
Product preparation issue	3	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Skin injuries NEC</i>		
Contusion	17	0
Scratch	1	0
Injuries SOC TOTAL	56	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	14	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF white blood cell count increased	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Coagulation and bleeding analyses</i>		
Activated partial thromboplastin time prolonged	1	0
Coagulation test abnormal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	1	0
<i>Faecal analyses NEC</i>		
Faecal volume increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	1	0
Heart rate decreased	1	0
Heart rate increased	8	0
<i>Immunology analyses NEC</i>		
Tryptase increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	2	0
Body temperature fluctuation	2	0
Body temperature increased	42	0
Breath sounds abnormal	1	0
Respiratory rate decreased	2	0
Respiratory rate increased	2	0
Weight decreased	2	0
<i>Platelet analyses</i>		
Platelet count increased	3	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	13	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	1	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>Toxicology laboratory analyses</i>		
Blood mercury abnormal	1	0
<i>Urinalysis NEC</i>		
Protein urine present	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	3	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Capillary nail refill test abnormal	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	7	0
Investigations SOC TOTAL	119	0

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Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	38	0
Hypophagia	4	0
Increased appetite	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	3	0
Food intolerance	2	0
<i>General nutritional disorders NEC</i>		
Failure to thrive	1	0
Feeding disorder	12	0
Food aversion	4	0
Poor feeding infant	43	0
Weight gain poor	4	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
<i>Zinc disorders</i>		
Zinc deficiency	1	0
Metabolic disorders SOC TOTAL	120	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>		
Arthralgia	3	0
Joint range of motion decreased	1	0
Joint swelling	8	0
<i>Muscle pains</i>		
Myalgia	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
Muscle swelling	1	0
Muscle twitching	7	0
<i>Muscle tone abnormalities</i>		
Floppy infant	29	0
Muscle rigidity	9	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Infantile back arching	1	0
Mobility decreased	1	0
Musculoskeletal stiffness	10	0
Posture abnormal	1	0
Toe walking	1	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	1	0
Musculoskeletal discomfort	1	0
Neck pain	1	0
Pain in extremity	23	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Muscle & tissue disorders SOC TOTAL	109	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	6	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>		
Aphasia	2	0
Dyspraxia	2	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	6	0
Lethargy	31	0
Loss of consciousness	18	0
Sedation	1	0
Somnolence	63	0
Syncope	16	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	19	0
Hypokinesia	2	0
Motor dysfunction	1	0
Movement disorder	2	0
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Dystonia	1	0
Opisthotonus	3	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	13	0
<i>Headaches NEC</i>		
Headache	5	0
Tension headache	1	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	3	0
<i>Muscle tone abnormal</i>		
Hypertonia	1	0
Hypotonia	63	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	12	0
<i>Nervous system disorders NEC</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Nervous system disorder	3	0
Neurological signs and symptoms NEC		
Agitation neonatal	2	0
Dizziness	2	0
Drooling	2	0
Exaggerated startle response	1	0
Fontanelle bulging	3	0
Grimacing	1	0
Hyporesponsive to stimuli	2	0
Myoclonus	2	0
Neurological decompensation	1	0
Neurological symptom	1	0
Pleocytosis	3	0
Presyncope	5	0
Unresponsive to stimuli	59	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	12	0
Olfactory nerve disorders		
Anosmia	1	0
Paraesthesias and dysaesthesias		
Hyperaesthesia	1	0
Hypoaesthesia	1	0
Seizures and seizure disorders NEC		
Epilepsy	7	0
Febrile convulsion	18	0
Infantile spasms	3	0
Myoclonic epilepsy	1	0
Partial seizures	7	0
Seizure	70	0
Seizure cluster	2	0
Seizure like phenomena	1	0
Status epilepticus	1	0
Sensory abnormalities NEC		
Ageusia	1	0
Dysgeusia	1	0
Neuralgia	1	0
Restless legs syndrome	1	0
Sensory disturbance	1	0
Taste disorder	1	0
Speech and language abnormalities		
Speech disorder	3	0
Speech disorder developmental	1	0
Structural brain disorders NEC		
Brain injury	2	1
Tremor (excl congenital)		
Tremor	13	0
Nervous system disorders SOC TOTAL	522	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	4	0
<i>Normal newborn status</i>		
Normal newborn	1	0
Pregnancy conditions SOC TOTAL	8	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	15	0
Breath holding	8	0
Regressive behaviour	1	0
Staring	10	0
<i>Anxiety symptoms</i>		
Agitation	10	0
Anxiety	4	0
Nervousness	3	0
Stress	2	0
Tension	1	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Disturbance in social behaviour	1	0
Personality change	4	0
Social avoidant behaviour	3	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	10	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Eating disorders NEC</i>		
Eating disorder	3	0
Selective eating disorder	4	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	19	0
Emotional poverty	1	0
Irritability	101	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
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	19	0
<i>Learning disorders</i>		
Learning disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	3	0
<i>Mood disorders NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Apathy	1	0
Listless	8	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Panic attacks and disorders</i>		
Panic reaction	1	0
<i>Parasomnias</i>		
Nightmare	1	0
Sleep terror	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	11	0
<i>Psychiatric elimination disorders</i>		
Enuresis	2	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	5	0
<i>Sleep disorders NEC</i>		
Sleep disorder	19	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>		
Suicidal ideation	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	298	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	2	0
Micturition urgency	1	0
Pollakiuria	1	0
Urinary incontinence	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
Renal & urinary disorders SOC TOTAL	7	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
Intermenstrual bleeding	2	0
Menstrual disorder	1	0
Menstruation irregular	4	0
<i>Menstruation with decreased bleeding</i>		
Hypomenorrhoea	1	0
Menstruation delayed	1	0
<i>Menstruation with increased bleeding</i>		
Polymenorrhoea	2	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Oedema genital	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	15	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	26	0
Apnoeic attack	7	0
Dyspnoea	37	0
Grunting	6	0
Hypopnoea	10	0
Hypoventilation	1	0
Irregular breathing	1	0
Respiratory arrest	19	1
Respiratory distress	4	0
Tachypnoea	6	0
<i>Bronchospasm and obstruction</i>		
Wheezing	16	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	1
<i>Coughing and associated symptoms</i>		
Cough	22	0
Productive cough	4	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary haemorrhage	1	0
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Neonatal hypoxic conditions</i>		
Infantile apnoea	3	0
Neonatal hypoxia	3	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>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	2	0
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	1
Respiratory disorder	10	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	6	0
Dysphonia	2	0
Nasal obstruction	1	0
Oropharyngeal pain	1	0
Rhinorrhoea	6	0
Sneezing	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	206	3

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Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	2	0
Alopecias		
Alopecia	1	0
Angioedemas		
Angioedema	3	0
Apocrine and eccrine gland disorders		
Cold sweat	10	0
Hyperhidrosis	8	0
Hypohidrosis	1	0
Miliaria	1	0
Bullous conditions		
Blister	16	0
Blood blister	2	0
Erythema multiforme	5	0
Pemphigoid	3	0
Dermal and epidermal conditions NEC		
Dry skin	7	0
Macule	1	0
Pain of skin	2	0
Papule	4	0
Scab	3	0
Skin burning sensation	1	0
Skin discolouration	34	0
Skin discomfort	1	0
Skin disorder	3	0
Skin induration	2	0
Skin lesion	3	0
Skin odour abnormal	1	0
Skin reaction	21	0
Skin sensitisation	1	0
Skin swelling	1	0
Skin tightness	2	0
Skin warm	20	0
Xanthelasma	1	0
Yellow skin	1	0
Dermatitis and eczema		
Dermatitis allergic	8	0
Dermatitis atopic	3	0
Dermatitis diaper	3	0
Eczema	19	0
Eczema infantile	1	0
Skin irritation	2	0
Erythemas		
Erythema	294	0
Exfoliative conditions		
Exfoliative rash	1	0
Skin exfoliation	3	0
Hypertrichoses		
Hypertrichosis	1	0
Pigmentation changes NEC		
Post inflammatory pigmentation change	1	0
Pilar disorders NEC		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Hair disorder	1	0
Pruritus NEC		
Pruritus	18	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Petechiae	50	0
Purpura	21	0
Rashes, eruptions and exanthems NEC		
Rash	162	0
Rash erythematous	19	0
Rash macular	63	0
Rash maculo-papular	12	0
Rash papular	11	0
Rash pruritic	5	0
Rash vesicular	1	0
Skin and subcutaneous conditions NEC		
Skin mass	2	0
Skin dystrophies		
Hypertrophic scar	1	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin vasculitides		
Vasculitic rash	3	0
Skin vasomotor conditions		
Livedo reticularis	17	0
Urticarias		
Urticaria	60	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	946	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>Contraceptive methods female</i>		
Contraceptive implant	1	0
<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	5	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	5	0
Hypoperfusion	1	0
Shock	7	0
<i>Haemorrhages NEC</i>		
Haematoma	2	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	51	0
Flushing	9	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	8	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	132	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	222	0
TOTAL REACTIONS FOR DRUG	5124	24
TOTAL REPORTS	1845	
TOTAL FATAL OUTCOME REPORTS		24