

**Case Series Drug Analysis Print**  
**Name: FOI 23/947: 6-in-1 vaccine**

Report Run Date: 05-Jan-2024

Data Lock Date: 03-Jan-2024 18:30:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 26.1

FOI 23/947: 6-in-1 vaccine: All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the 6-in-1 vaccine from 01/01/2017 up to and including 31/12/2023

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Leukocytoses NEC</b></i>		
Lymphocytic infiltration	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymphadenopathy	3	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Myelosuppression	1	0
<i><b>Neutropenias</b></i>		
Neutropenia	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	8	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac arrest neonatal	1	1
Cardio-respiratory arrest	3	2
Ventricular fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>16</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Oral cavity disorders congenital NEC</i>		
Tethered oral tissue	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Earliest Reaction Date: 27-Jan-2015

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	1	0
Ear swelling	4	0
<b>Ear disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Cataract conditions</b></i>		
Cataract	1	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	1	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haemorrhage	1	0
<i><b>Ocular disorders NEC</b></i>		
Dark circles under eyes	1	0
Eye oedema	1	0
Eye swelling	1	0
Ocular discomfort	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	3	0
Gaze palsy	3	0
Strabismus	1	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	1	0
<i><b>Pupil disorders</b></i>		
Miosis	1	0
Mydriasis	1	0
<i><b>Visual disorders NEC</b></i>		
Vision blurred	1	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	51	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	5	0
Faecaloma	1	0
Faeces discoloured	11	0
Faeces hard	1	0
Faeces pale	1	0
Mucous stools	8	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	7	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	11	0
Abdominal pain upper	14	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	13	0
Gastrooesophageal reflux disease	7	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Infant dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	4	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discolouration	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	3	0
Retching	1	0
Vomiting	50	0
Vomiting projectile	16	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	6	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Salivary gland enlargements</i>		
Salivary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Protrusion tongue	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>228</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	7	0
Decreased activity	1	0
Fatigue	8	0
Malaise	14	0
<i><b>Body temperature altered</b></i>		
Hyperthermia	1	0
<i><b>Death and sudden death</b></i>		
Death	7	7
Sudden death	4	4
Sudden infant death syndrome	4	4
<i><b>Febrile disorders</b></i>		
Pyrexia	144	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	6	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	5	0
Thirst decreased	2	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	2	0
Gait inability	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	2	0
Crying	75	0
Developmental delay	2	0
Developmental regression	1	0
Glassy eyes	3	0
High-pitched crying	12	0
Illness	4	0
Induration	2	0
Influenza like illness	1	0
Moaning	2	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	20	0
Screaming	23	0
Secretion discharge	1	0
Swelling	10	0
Swelling face	5	0
<i><b>Inflammations</b></i>		
Inflammation	10	0
Systemic inflammatory response syndrome	1	0
<i><b>Injection site reactions</b></i>		
Injection site discolouration	1	0
Injection site erythema	1	0
Injection site induration	1	0
Injection site mass	4	0
Injection site pain	1	0
Injection site pruritus	1	0
Injection site reaction	1	0
Injection site swelling	3	0
Injection site vesicles	1	0
<i><b>Oedema NEC</b></i>		



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Oedema	1	0
Oedema peripheral	1	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	1	0
Discomfort	7	0
Pain	25	0
Tenderness	2	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Drug ineffective	1	0
Vaccination failure	5	0
<b><i>Vaccination site reactions</i></b>		
Extensive swelling of vaccinated limb	3	0
Vaccination site discomfort	1	0
Vaccination site erythema	15	0
Vaccination site haemorrhage	1	0
Vaccination site induration	2	0
Vaccination site inflammation	5	0
Vaccination site mass	12	0
Vaccination site pain	8	0
Vaccination site pruritus	1	0
Vaccination site rash	4	0
Vaccination site swelling	11	0
Vaccination site vesicles	1	0
Vaccination site warmth	3	0
<b>General disorders SOC TOTAL</b>	<b>507</b>	<b>15</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
Jaundice cholestatic	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergy to metals	1	0
Hypersensitivity	9	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	2	0
Food allergy	4	0
Milk allergy	3	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	10	0
Anaphylactic shock	1	0
<i><b>Atopic disorders</b></i>		
Atopy	1	0
Seasonal allergy	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	2	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
<i><b>Immunodeficiency disorders NEC</b></i>		
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>37</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	8	0
Meningitis bacterial	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i><b>Bordetella infections</b></i>		
Pertussis	2	0
<i><b>Central nervous system and spinal infections</b></i>		
Meningitis	2	0
Meningitis aseptic	2	0
<i><b>Ear infections</b></i>		
Ear infection	1	0
<i><b>Enteroviral infections NEC</b></i>		
Meningitis enteroviral	1	0
<i><b>Haemophilus infections</b></i>		
Haemophilus infection	4	0
Meningitis haemophilus	1	0
<i><b>Infections NEC</b></i>		
Abscess	3	0
Abscess limb	2	0
Infection	2	0
Vaccination site abscess	1	0
Vaccination site infection	2	0
<i><b>Influenza viral infections</b></i>		
Influenza	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Lower respiratory tract infection	1	0
Pneumonia	1	0
Pneumonia aspiration	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Eczema infected	1	0
Skin infection	3	0
<i><b>Staphylococcal infections</b></i>		
Staphylococcal infection	1	0
<i><b>Upper respiratory tract infections</b></i>		
Croup infectious	1	0
Nasopharyngitis	1	0
Tonsillitis	1	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	2	0
<i><b>Viral infections NEC</b></i>		
Bronchiolitis	3	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>54</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	2	0
Maternal exposure during breast feeding	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	6	0
Product use in unapproved indication	1	0
Wrong technique in product usage process	3	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Muscle injury	2	0
<i><b>Non-site specific injuries NEC</b></i>		
Wound secretion	1	0
<i><b>Overdoses NEC</b></i>		
Overdose	1	0
<i><b>Product administration errors and issues</b></i>		
Accidental overdose	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	6	0
Incorrect route of product administration	1	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	3	0
<i><b>Product preparation errors and issues</b></i>		
Product preparation error	1	0
Product preparation issue	6	0
<i><b>Product prescribing errors and issues</b></i>		
Product prescribing error	1	0
<i><b>Product storage errors and issues in the product use system</b></i>		
Product storage error	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	7	0
Scratch	1	0
Skin injury	1	0
<b>Injuries SOC TOTAL</b>	<b>49</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	2	0
<i><b>Cardiac function diagnostic procedures</b></i>		
Cardiac output decreased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	1	0
Heart rate increased	2	0
Pulse abnormal	1	0
<i><b>Hepatobiliary function diagnostic procedures</b></i>		
Alanine aminotransferase increased	1	0
<i><b>Immunoglobulin analyses</b></i>		
Blood immunoglobulin G increased	2	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood magnesium decreased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	9	0
Breath sounds abnormal	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	4	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	2	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin decreased	1	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output decreased	3	0
<i><b>White blood cell analyses</b></i>		
Lymphocyte count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>36</b>	<b>0</b>

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Data Lock Date: 03-Jan-2024 18:30:03  
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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	1	0
Decreased appetite	29	0
Food refusal	2	0
Hypophagia	2	0
Increased appetite	1	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	4	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Dairy intolerance	1	0
Food intolerance	2	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	1	0
Food aversion	1	0
Poor feeding infant	21	0
Weight gain poor	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Lactic acidosis	1	0
Metabolic acidosis	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>69</b>	<b>0</b>

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Data Lock Date: 03-Jan-2024 18:30:03  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Joint swelling	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	4	0
Muscle tightness	1	0
Muscle twitching	2	0
<i>Muscle tone abnormalities</i>		
Floppy infant	18	0
Muscle rigidity	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Infantile back arching	4	0
Limb mass	1	0
Musculoskeletal stiffness	5	0
Posture abnormal	1	0
Weight bearing difficulty	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Flank pain	1	0
Musculoskeletal pain	1	0
Pain in extremity	10	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>58</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	4	0
<i><b>Coordination and balance disturbances</b></i>		
Balance disorder	2	0
Nystagmus	1	0
<i><b>Cortical dysfunction NEC</b></i>		
Aphasia	1	0
<i><b>Disturbances in consciousness NEC</b></i>		
Depressed level of consciousness	1	0
Lethargy	10	0
Loss of consciousness	3	0
Postictal state	1	0
Somnolence	32	0
Syncope	4	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Dyskinesia	8	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
<i><b>Eye movement disorders</b></i>		
VIth nerve paralysis	1	0
<i><b>Generalised tonic-clonic seizures</b></i>		
Generalised tonic-clonic seizure	5	0
<i><b>Headaches NEC</b></i>		
Headache	2	0
<i><b>Intellectual disabilities</b></i>		
Intellectual disability	1	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Cognitive disorder	1	0
Mental impairment	1	0
<i><b>Muscle tone abnormal</b></i>		
Hypotonia	9	0
<i><b>Narcolepsy and hypersomnia</b></i>		
Hypersomnia	1	0
<i><b>Nervous system disorders NEC</b></i>		
Nervous system disorder	1	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	1	0
Hyporesponsive to stimuli	3	0
Infant irritability	1	0
Myoclonus	1	0
Neurological symptom	1	0
Slow response to stimuli	1	0
Unresponsive to stimuli	26	0
<i><b>Neuromuscular disorders NEC</b></i>		
Hypotonic-hyporesponsive episode	18	0
Muscle spasticity	1	0
<i><b>Paralysis and paresis (excl cranial nerve)</b></i>		
Paralysis	1	0
<i><b>Seizures and seizure disorders NEC</b></i>		
Epilepsy	1	0
Epileptic encephalopathy	1	0
Febrile convulsion	11	0
Infantile spasms	3	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Seizure	18	0
Status epilepticus	1	0
<b><i>Sleep disturbances NEC</i></b>		
Sudden onset of sleep	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	1	0
Speech disorder	2	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	4	0
<b>Nervous system disorders SOC TOTAL</b>	<b>188</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Gestational age and weight conditions</i>		
Poor weight gain neonatal	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product quality issue	5	0
<b>null SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	8	0
Behaviour disorder	1	0
Breath holding	3	0
Staring	4	0
<b><i>Affect alterations NEC</i></b>		
Flat affect	1	0
<b><i>Anxiety disorders NEC</i></b>		
Separation anxiety disorder	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	6	0
Anxiety	2	0
Nervousness	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Personality change	1	0
Social avoidant behaviour	2	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	1	0
<b><i>Communications disorders</i></b>		
Communication disorder	1	0
Mutism	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	9	0
Middle insomnia	1	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	5	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	2	0
Emotional distress	4	0
Irritability	44	0
Mood altered	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Phonophobia	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	14	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Decreased interest	1	0
Depressed mood	1	0
<b><i>Mood disorders NEC</i></b>		
Listless	3	0
<b><i>Panic attacks and disorders</i></b>		
Panic reaction	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	2	0
<b><i>Psychiatric symptoms NEC</i></b>		
Decreased eye contact	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	8	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Intentional self-injury	1	0
<b><i>Tic disorders</i></b>		

# Case Series Drug Analysis Print

## Name: FOI 23/947: 6-in-1 vaccine

Report Run Date: 05-Jan-2024

Data Lock Date: 03-Jan-2024 18:30:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <sup>Psychiatric disorders cont'd</sup>		
Tic	2	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>135</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: FOI 23/947: 6-in-1 vaccine

Report Run Date: 05-Jan-2024

Data Lock Date: 03-Jan-2024 18:30:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Anuria	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

# Case Series Drug Analysis Print

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Report Run Date: 05-Jan-2024

Data Lock Date: 03-Jan-2024 18:30:03

Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital blister	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>



# Case Series Drug Analysis Print

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 Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 03-Jan-2024 18:30:03  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	12	0
Dyspnoea	15	0
Hypopnoea	4	0
Irregular breathing	1	0
Respiration abnormal	3	0
Respiratory arrest	4	0
Respiratory distress	2	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Wheezing	3	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Cyanosis central	1	0
Respiratory acidosis	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	12	0
Haemoptysis	1	0
Productive cough	3	0
Sputum discoloured	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	2	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	3	0
<i><b>Neonatal hypoxic conditions</b></i>		
Brief resolved unexplained event	1	0
Infantile apnoea	3	0
Neonatal hypoxia	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Use of accessory respiratory muscles	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Choking	1	0
Dysphonia	1	0
Oropharyngeal pain	2	0
Rhinorrhoea	4	0
<b>Respiratory disorders SOC TOTAL</b>	<b>86</b>	<b>0</b>

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Report Run Date: 05-Jan-2024  
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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	2	0
Hyperhidrosis	3	0
<b><i>Bullous conditions</i></b>		
Blister	4	0
Dermatitis bullous	1	0
Pemphigoid	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	4	0
Papule	3	0
Skin burning sensation	1	0
Skin discolouration	13	0
Skin disorder	1	0
Skin induration	2	0
Skin lesion	1	0
Skin plaque	1	0
Skin reaction	2	0
Skin warm	7	0
Skin weeping	1	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	1	0
Dermatitis allergic	4	0
Dermatitis atopic	3	0
Dermatitis diaper	1	0
Eczema	12	0
Eczema asteatotic	1	0
Eczema infantile	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	38	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	7	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	15	0
Purpura	4	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	68	0
Rash erythematous	17	0
Rash macular	17	0
Rash papular	7	0
Rash pruritic	3	0
Rash vesicular	5	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	1	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin erosion	1	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	12	0
<b><i>Urticarias</i></b>		
Urticaria	23	0

# Case Series Drug Analysis Print

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Urticaria chronic	1	0
Urticaria pressure	1	0
<b>Skin disorders SOC TOTAL</b>	<b>292</b>	<b>0</b>

# Case Series Drug Analysis Print

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Earliest Reaction Date: 27-Jan-2015

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Therapeutic procedures NEC</i>		
Injection	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	1
<i>Circulatory collapse and shock</i>		
Circulatory collapse	3	0
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Fibromuscular dysplasia	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	11	0
Flushing	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	5	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	45	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>70</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>1875</b>	<b>21</b>
<b>TOTAL REPORTS</b>	<b>688</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>21</b>