

## Case Series Drug Analysis Print

### Name: Rotavirus Vaccine Analysis Print

Report Run Date: 14-Oct-2022

Data Lock Date: 05-Oct-2022

Earliest Reaction Date: 20-Jun-2008

MedDRA Version: MedDRA 25.0

Rotavirus Vaccine  
Analysis Print: FOI 22/981 - All UK spontaneous suspected Adverse  
Drug Reaction (ADR) reports for Rotavirus vaccine up  
to and including 05/10/2022

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	1	0
<b><i>Haematological disorders</i></b>		
Mastocytosis	1	0
<b><i>Leukocytoses NEC</i></b>		
Lymphocytic infiltration	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymphadenitis	1	0
Lymphadenopathy	2	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Myelosuppression	1	0
<b><i>Neutropenias</i></b>		
Neutropenia	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	2	0
Thrombocytopenia	3	0
<b>Blood disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac disorders NEC</i>		
Cardiovascular disorder	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
Pericardial haemorrhage	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	5	0
Bradycardia neonatal	1	0
Tachycardia	8	0
<i>Supraventricular arrhythmias</i>		
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	4	2
Cardiac arrest neonatal	1	1
Cardio-respiratory arrest	4	1
Ventricular fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>28</b>	<b>4</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Congenital disorders</b>		
<i>Gastric disorders congenital</i>		
Pyloric stenosis	1	0
<i>Immune system abnormalities congenital</i>		
Omenn syndrome	2	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acrodermatitis enteropathica	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	1	0
<b>Ear disorders SOC TOTAL</b>	<b>3</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>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Swelling of eyelid	1	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haemorrhage	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye oedema	1	0
Eye swelling	1	0
Periorbital oedema	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Ocular hyperaemia	3	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	5	0
Strabismus	1	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	1	0
<i><b>Pupil disorders</b></i>		
Miosis	1	0
Mydriasis	2	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Cortical visual impairment	1	0
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>21</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	4	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
<i>Anal and rectal signs and symptoms</i>		
Rectal discharge	1	0
Rectal tenesmus	3	0
<i>Colitis (excl infective)</i>		
Allergic colitis	1	0
Colitis	1	0
Necrotising colitis	4	2
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	374	0
Diarrhoea haemorrhagic	14	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
Epigastric discomfort	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	27	0
Faecaloma	1	0
Faeces discoloured	43	0
Faeces hard	1	0
Faeces soft	1	0
Mucous stools	47	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	23	0
Aerophagia	1	0
Flatulence	67	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	89	0
Abdominal pain lower	1	0
Abdominal pain upper	79	0
Abdominal rigidity	2	0
Abdominal tenderness	2	0
Gastrointestinal pain	1	0
Infantile colic	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	68	0
Duodenogastric reflux	1	0
Gastrooesophageal reflux disease	33	0
Infrequent bowel movements	4	0
Intestinal dilatation	3	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	3	0
Gastrointestinal disorder	5	0
<i>Gastrointestinal dyskinetic disorders</i>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Bowel movement irregularity	8	0
Change of bowel habit	4	0
Dyschezia	4	0
Gastrointestinal motility disorder	6	0
Infant dyschezia	1	0
<b>Gastrointestinal inflammatory disorders NEC</b>		
Enterocolitis	1	0
Gastrointestinal inflammation	1	0
Gastrointestinal tract irritation	1	0
Necrotising enterocolitis neonatal	3	1
<b>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</b>		
Gastrointestinal necrosis	2	0
<b>Gastrointestinal signs and symptoms NEC</b>		
Abdominal discomfort	25	0
Dysphagia	3	0
<b>Gastrointestinal spastic and hypermotility disorders</b>		
Frequent bowel movements	16	0
<b>Gastrointestinal stenosis and obstruction NEC</b>		
Intestinal obstruction	1	0
Intussusception	65	0
Volvulus	1	0
<b>Gastrointestinal vascular occlusion and infarction</b>		
Intestinal ischaemia	1	0
<b>Gingival disorders, signs and symptoms NEC</b>		
Gingival swelling	1	0
Noninfective gingivitis	1	0
<b>Intestinal haemorrhages</b>		
Rectal haemorrhage	16	0
<b>Nausea and vomiting symptoms</b>		
Discoloured vomit	1	0
Infantile spitting up	4	0
Infantile vomiting	5	0
Nausea	5	0
Regurgitation	4	0
Retching	24	0
Vomiting	228	0
Vomiting projectile	31	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Haematemesis	3	0
Haematochezia	112	0
Melaena	3	0
<b>Oesophagitis (excl infective)</b>		
Eosinophilic oesophagitis	1	0
Oesophagitis	1	0
<b>Oral dryness and saliva altered</b>		
Salivary hypersecretion	2	0
<b>Oral soft tissue disorders NEC</b>		
Lip blister	1	0
<b>Oral soft tissue signs and symptoms</b>		
Lip discolouration	1	0
Lip erythema	1	0
Oral discomfort	1	0
Oral mucosal blistering	1	0



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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Oral mucosal discolouration	1	0
<b>Oral soft tissue swelling and oedema</b>		
Lip swelling	5	0
<b>Salivary gland enlargements</b>		
Salivary gland enlargement	1	0
<b>Stomatitis and ulceration</b>		
Stomatitis	2	0
<b>Tongue signs and symptoms</b>		
Swollen tongue	5	0
Tongue discomfort	1	0
Tongue movement disturbance	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>1521</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Application and instillation site reactions</i>		
Application site irritation	1	0
<i>Asthenic conditions</i>		
Asthenia	5	0
Decreased activity	1	0
Fatigue	10	0
Malaise	42	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	9	9
Sudden death	3	3
Sudden infant death syndrome	6	5
<i>Febrile disorders</i>		
Pyrexia	159	0
<i>Feelings and sensations NEC</i>		
Chills	5	0
Feeling abnormal	9	0
Feeling cold	2	0
Feeling hot	5	0
Feeling jittery	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	10	0
Crying	120	0
Developmental delay	1	0
Discharge	1	0
Foaming at mouth	1	0
General physical health deterioration	2	0
Glassy eyes	2	0
High-pitched crying	8	0
Illness	24	0
Induration	2	0
Irritability postvaccinal	3	0
Moaning	2	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	10	0
Screaming	52	0
Secretion discharge	4	0
Swelling	1	0
Swelling face	5	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site erythema	2	0
Injection site vesicles	1	0
<i>Oedema NEC</i>		
Oedema	1	0
Oedema peripheral	2	0
<i>Pain and discomfort NEC</i>		

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Chest pain	1	0
Discomfort	17	0
Pain	48	0
Tenderness	1	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse drug reaction	11	0
Drug ineffective	1	0
Vaccination failure	5	0
<b><i>Vaccination site reactions</i></b>		
Vaccination site bruising	1	0
Vaccination site erythema	2	0
Vaccination site granuloma	1	0
Vaccination site haematoma	1	0
Vaccination site mass	7	0
Vaccination site pain	1	0
Vaccination site rash	1	0
Vaccination site reaction	1	0
Vaccination site scar	1	0
Vaccination site swelling	3	0
<b>General disorders SOC TOTAL</b>	<b>622</b>	<b>17</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatosplenomegaly	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	10	0
Multiple allergies	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Food allergy	3	0
Milk allergy	8	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	19	0
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Atopy	1	0
<i>Immune and associated conditions NEC</i>		
Graft versus host disease	1	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>52</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Diarrhoea infectious	1	0
Gastroenteritis	4	0
Peritonitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Bacterial infection	1	0
Meningitis bacterial	2	0
Skin bacterial infection	1	0
<b><i>Bordetella infections</i></b>		
Pertussis	1	0
<b><i>Candida infections</i></b>		
Oral candidiasis	2	0
<b><i>Central nervous system and spinal infections</i></b>		
Meningitis	3	0
Meningitis aseptic	5	0
<b><i>Cytomegaloviral infections</i></b>		
Disseminated cytomegaloviral infection	1	0
<b><i>Ear infections</i></b>		
Ear infection	1	0
Otitis media	1	0
<b><i>Enteroviral infections NEC</i></b>		
Meningitis enteroviral	2	0
<b><i>Escherichia infections</i></b>		
Escherichia infection	1	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	2	0
<b><i>Infectious transmissions</i></b>		
Infection via vaccinee	20	0
Secondary transmission	1	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	1	0
Lower respiratory tract infection	3	0
Pneumonia	1	0
Pneumonia aspiration	1	0
<b><i>Pneumocystis infections</i></b>		
Pneumocystis jirovecii infection	2	0
Pneumocystis jirovecii pneumonia	1	0
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	10	0
Rotavirus infection	25	0
<b><i>Salmonella infections</i></b>		
Salmonellosis	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	10	0
<b><i>Skin structures and soft tissue infections</i></b>		
Eczema infected	1	0
Skin infection	1	0
<b><i>Streptococcal infections</i></b>		
Toxic shock syndrome streptococcal	1	0
<b><i>Upper respiratory tract infections</i></b>		
Croup infectious	1	0
Nasopharyngitis	1	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Rhinitis	1	0
<b>Urinary tract infections</b>		
Kidney infection	2	0
Urinary tract infection	4	0
<b>Viral infections NEC</b>		
Bronchiolitis	4	0
Gastritis viral	1	0
Gastroenteritis viral	3	0
Viral infection	3	0
<b>Infections SOC TOTAL</b>	<b>129</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to vaccinated person	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	4	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
Wound secretion	1	0
<i>Product administration errors and issues</i>		
Accidental underdose	3	0
Extra dose administered	3	0
Inappropriate schedule of product administration	3	0
Incomplete course of vaccination	1	0
Product administered to patient of inappropriate age	3	0
Wrong product administered	1	0
<i>Product preparation errors and issues</i>		
Product preparation issue	1	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	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	10	0
Scratch	1	0
Skin abrasion	1	0
Skin injury	1	0
<i>Underdoses NEC</i>		
Underdose	2	0
<b>Injuries SOC TOTAL</b>	<b>44</b>	<b>0</b>



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<b>Investigations</b>		
<i><b>Bacteria identification and serology (excl mycobacteria)</b></i>		
Bacterial test positive	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	10	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	1	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF white blood cell count increased	1	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	1	0
Heart rate increased	7	0
Heart rate irregular	1	0
Pulse abnormal	1	0
<i><b>Hepatobiliary function diagnostic procedures</b></i>		
Bilirubin conjugated increased	1	0
Blood bilirubin increased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	1	0
Body temperature abnormal	4	0
Body temperature decreased	1	0
Body temperature fluctuation	3	0
Body temperature increased	24	0
Breath sounds abnormal	1	0
Respiratory rate decreased	3	0
Respiratory rate increased	6	0
Weight decreased	7	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	12	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin decreased	1	0
<i><b>Respiratory tract and thoracic imaging procedures</b></i>		
Chest X-ray abnormal	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	1	0
White blood cells urine	1	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output decreased	2	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Capillary nail refill test abnormal	1	0
<i><b>Virus identification and serology</b></i>		
Rotavirus test positive	4	0
<i><b>White blood cell analyses</b></i>		
Lymphocyte count increased	1	0
Neutrophil count decreased	1	0
White blood cell count increased	3	0
<b>Investigations SOC TOTAL</b>	<b>104</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	2	0
Decreased appetite	33	0
Food refusal	3	0
Hypophagia	6	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	8	0
Food intolerance	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	6	0
Failure to thrive	3	0
Feeding disorder	7	0
Food aversion	3	0
Poor feeding infant	48	0
Weight gain poor	9	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Metabolic acidosis	2	0
<i><b>Potassium imbalance</b></i>		
Hyperkalaemia	1	0
<i><b>Sugar intolerance (excl glucose intolerance)</b></i>		
Lactose intolerance	16	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	10	0
<i><b>Zinc disorders</b></i>		
Zinc deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>164</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Joint related signs and symptoms</i>		
Arthralgia	1	0
<i>Muscle pains</i>		
Myalgia	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	4	0
Muscle twitching	4	0
<i>Muscle tone abnormalities</i>		
Floppy infant	40	0
Muscle rigidity	1	0
Trismus	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Chest wall mass	1	0
Infantile back arching	3	0
Musculoskeletal stiffness	5	0
Posture abnormal	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Limb discomfort	1	0
Musculoskeletal pain	1	0
Pain in extremity	4	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>68</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b>Absence seizures</b>		
Petit mal epilepsy	2	0
<b>Autonomic nervous system disorders</b>		
Autonomic nervous system imbalance	1	0
<b>Disturbances in consciousness NEC</b>		
Depressed level of consciousness	5	0
Lethargy	19	0
Loss of consciousness	10	0
Postictal state	1	0
Somnolence	43	0
Syncope	7	0
<b>Dyskinesias and movement disorders NEC</b>		
Dyskinesia	8	0
Hypokinesia	1	0
Movement disorder	2	0
<b>Dystonias</b>		
Opisthotonus	3	0
<b>Encephalopathies toxic and metabolic</b>		
Metabolic encephalopathy	1	0
<b>Eye movement disorders</b>		
VIth nerve paralysis	1	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	7	0
<b>Headaches NEC</b>		
Headache	1	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Disturbance in attention	2	0
<b>Muscle tone abnormal</b>		
Hypotonia	38	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	5	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	2	0
<b>Neurological signs and symptoms NEC</b>		
Drooling	1	0
Exaggerated startle response	1	0
Fontanelle bulging	2	0
Fontanelle depressed	2	0
Hyporesponsive to stimuli	2	0
Infant irritability	2	0
Myoclonus	2	0
Neurological decompensation	1	0
Pleocytosis	2	0
Slow response to stimuli	1	0
Unresponsive to stimuli	57	0
<b>Neuromuscular disorders NEC</b>		
Hypotonic-hyporesponsive episode	7	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	4	0
Febrile convulsion	10	0
Infantile spasms	3	0
Partial seizures	3	0
Seizure	21	0

# Case Series Drug Analysis Print

## Name: Rotavirus Vaccine Analysis Print

Report Run Date: 14-Oct-2022

Data Lock Date: 05-Oct-2022

Earliest Reaction Date: 20-Jun-2008

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Seizure cluster	1	0
Seizure like phenomena	2	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>		
Speech disorder	3	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	5	0
<b>Nervous system disorders SOC TOTAL</b>	<b>293</b>	<b>0</b>

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MedDRA Version: MedDRA 25.0

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Pregnancy conditions</b>		
<i>Neonatal metabolic and endocrine disorders</i>		
Hypothermia neonatal	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>2</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b><i>Product physical issues</i></b>		
Liquid product physical issue	1	0
<b><i>Product quality issues NEC</i></b>		
Product quality issue	22	0
<b>null SOC TOTAL</b>	<b>23</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	17	0
Behaviour disorder	1	0
Breath holding	7	0
Regressive behaviour	2	0
Staring	4	0
<b><i>Anxiety symptoms</i></b>		
Agitation	7	0
Anxiety	1	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Personality change	1	0
Social avoidant behaviour	2	0
<b><i>Communications disorders</i></b>		
Communication disorder	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	11	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	7	0
<b><i>Eating disorders NEC</i></b>		
Selective eating disorder	7	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional disorder	2	0
Emotional distress	11	0
Irritability	74	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	1	0
Hallucinations, mixed	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	28	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	2	0
<b><i>Mood disorders NEC</i></b>		
Apathy	1	0
Listless	6	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	1	0
Panic reaction	1	0
<b><i>Parasomnias</i></b>		
Sleep terror	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	3	0
<b><i>Psychiatric symptoms NEC</i></b>		
Decreased eye contact	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	13	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>215</b>	<b>0</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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MedDRA Version: MedDRA 25.0

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

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	30	0
Apnoeic attack	5	0
Dyspnoea	45	0
Grunting	2	0
Hyperventilation	2	0
Hypopnoea	9	0
Respiration abnormal	5	0
Respiratory arrest	14	0
Respiratory distress	5	0
Tachypnoea	3	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
<i><b>Coughing and associated symptoms</b></i>		
Cough	14	0
Haemoptysis	1	0
Productive cough	1	0
Sputum discoloured	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Reflux laryngitis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Rales	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	3	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	2	0
<i><b>Neonatal hypoxic conditions</b></i>		
Brief resolved unexplained event	1	0
Cyanosis neonatal	1	0
Infantile apnoea	4	0
Neonatal hypoxia	5	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Respiratory symptom	1	0
Use of accessory respiratory muscles	2	0
<i><b>Respiratory tract disorders NEC</b></i>		
Aspiration	2	0
Respiratory disorder	2	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Choking	14	0
Choking sensation	1	0
Increased viscosity of upper respiratory secretion	1	0
Nasal obstruction	1	0
Oropharyngeal pain	2	0
Rhinorrhoea	6	0
Sneezing	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>193</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	3	0
Hyperhidrosis	4	0
<i><b>Bullous conditions</b></i>		
Blister	4	0
Dermatitis bullous	1	0
Erythema multiforme	1	0
Pemphigoid	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	5	0
Papule	4	0
Scab	1	0
Skin discolouration	17	0
Skin disorder	1	0
Skin fissures	1	0
Skin lesion	1	0
Skin plaque	1	0
Skin reaction	2	0
Skin warm	4	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis	1	0
Dermatitis allergic	5	0
Dermatitis atopic	2	0
Dermatitis diaper	2	0
Eczema	15	0
Eczema infantile	1	0
<i><b>Dermatitis ascribed to specific agent</b></i>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<i><b>Erythemas</b></i>		
Erythema	52	0
<i><b>Exfoliative conditions</b></i>		
Skin exfoliation	1	0
<i><b>Hypertrichoses</b></i>		
Hypertrichosis	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	6	0
<i><b>Purpura and related conditions</b></i>		
Henoch-Schonlein purpura	1	0
Petechiae	15	0
Purpura	6	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	58	0
Rash erythematous	7	0
Rash macular	14	0
Rash maculo-papular	2	0
Rash papular	4	0
Rash pruritic	3	0
Rash vesicular	1	0
<i><b>Skin and subcutaneous conditions NEC</b></i>		
Skin mass	1	0
<i><b>Skin haemorrhages</b></i>		
Skin haemorrhage	1	0
<i><b>Skin vasomotor conditions</b></i>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Livedo reticularis	17	0
<b>Urticarias</b>		
Urticaria	15	0
Urticaria pressure	1	0
<b>Skin disorders SOC TOTAL</b>	<b>284</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Dietary and nutritional therapies</i>		
Parenteral nutrition	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><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	5	0
Hypoperfusion	1	0
Shock	3	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	1	0
Haemorrhage	3	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Fibromuscular dysplasia	1	1
<i><b>Non-site specific vascular disorders NEC</b></i>		
Microangiopathy	1	0
Venocclusive disease	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	23	0
Flushing	1	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	7	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	83	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>132</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>3922</b>	<b>26</b>
<b>TOTAL REPORTS</b>	<b>1429</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>26</b>