

# Case Series Drug Analysis Print

**Name: Rotavirus**

Report Run Date: 21-Feb-2014  
Data Lock Date: 19-Feb-2014 23:39:39  
Earliest Reaction Date: 20-Jun-2008  
MedDRA Version: MedDRA 16.1  
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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	3	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<b><i>Anal and rectal disorders NEC</i></b>		
Anal fissure	1	0
<b><i>Colitis (excl infective)</i></b>		
Necrotising colitis	1	0
<b><i>Diarrhoea (excl infective)</i></b>		
Diarrhoea	83	0
Diarrhoea haemorrhagic	4	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Epigastric discomfort	1	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	5	0
Faeces discoloured	8	0
Mucous stools	4	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	6	0
Flatulence	6	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal pain	13	0
Abdominal pain lower	1	0
Abdominal pain upper	5	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	4	0
Gastrooesophageal reflux disease	3	0
Infrequent bowel movements	1	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	2	0
Gastrointestinal motility disorder	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	4	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Frequent bowel movements	2	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intussusception	8	0
<b><i>Intestinal haemorrhages</i></b>		
Rectal haemorrhage	2	0
<b><i>Large intestinal stenosis and obstruction</i></b>		
Volvulus	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	1	0
Regurgitation	1	0
Vomiting	50	0
Vomiting projectile	6	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Haematemesis	1	0
Haematochezia	22	0
<b><i>Stomatitis and ulceration</i></b>		
Stomatitis	1	0
<b><i>Tongue signs and symptoms</i></b>		
Swollen tongue	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>250</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Malaise	7	0
<i><b>Death and sudden death</b></i>		
Death	1	1
Sudden infant death syndrome	1	1
<i><b>Febrile disorders</b></i>		
Pyrexia	11	0
<i><b>Feelings and sensations NEC</b></i>		
Feeling abnormal	3	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	1	0
Crying	12	0
General physical health deterioration	1	0
Glassy eyes	1	0
Irritability	7	0
Local swelling	2	0
<i><b>Injection site reactions</b></i>		
Injection site erythema	1	0
<i><b>Pain and discomfort NEC</b></i>		
Discomfort	2	0
Pain	4	0
Tenderness	1	0
<b>General disorders SOC TOTAL</b>	<b>55</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	1	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	4	0
<b>Immune system disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Gastroenteritis	1	0
<i><b>Enteroviral infections NEC</b></i>		
Meningitis enteroviral	1	0
<i><b>Infectious transmissions</b></i>		
Infection via vaccinee	4	0
Secondary transmission	1	0
<i><b>Rotaviral infections</b></i>		
Rotavirus infection	4	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
<i><b>Urinary tract infections</b></i>		
Kidney infection	1	0
<i><b>Viral infections NEC</b></i>		
Gastroenteritis viral	2	0
<b>Infections SOC TOTAL</b>	<b>15</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Exposures to agents or circumstances NEC</i>		
Exposure to vaccinated person	1	0
<b>Injuries SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Bacteria identification and serology (excl mycobacteria)</b></i>		
Bacterial test positive	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate increased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature increased	2	0
Respiratory rate decreased	1	0
Weight decreased	1	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	3	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	1	0
White blood cells urine	1	0
<i><b>Virus identification and serology</b></i>		
Rotavirus test positive	2	0
<b>Investigations SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	5	0
Hypophagia	1	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Cow's milk intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	2	0
Feeding disorder neonatal	3	0
Feeding disorder of infancy or early childhood	2	0
Weight gain poor	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle related signs and symptoms NEC</i>		
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	2	0
Trismus	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Musculoskeletal pain	1	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Musculoskeletal stiffness	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	2	0
Somnolence	3	0
Syncope	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	7	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Neurological signs and symptoms NEC</i>		
Unresponsive to stimuli	1	0
<i>Seizures and seizure disorders NEC</i>		
Convulsion	3	0
Epilepsy	1	0
Partial seizures	1	0
Seizure cluster	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>23</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
Breath holding	2	0
<i>Behaviour and socialisation disturbances</i>		
Personality change	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Eating disorders NEC</i>		
Food aversion	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Emotional distress	4	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Panic attacks and disorders</i>		
Panic reaction	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Speech articulation and rhythm disturbances</i>		
Screaming	7	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	2	0
Dyspnoea	1	0
Respiratory arrest	2	0
<i><b>Respiratory tract disorders NEC</b></i>		
Aspiration	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Choking	2	0
Oropharyngeal pain	1	0
Rhinorrhoea	1	0
Sneezing	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Swelling face	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Skin discolouration	2	0
<i>Dermatitis and eczema</i>		
Eczema	1	0
<i>Erythemas</i>		
Erythema	2	0
Rash erythematous	1	0
<i>Papulosquamous conditions</i>		
Rash papular	1	0
<i>Pruritus NEC</i>		
Pruritus generalised	1	0
<i>Purpura and related conditions</i>		
Petechiae	2	0
Purpura	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	4	0
Rash generalised	2	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Urticarias</i>		
Urticaria	2	0
<b>Skin disorders SOC TOTAL</b>	<b>23</b>	<b>0</b>



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<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Hypoperfusion	1	0
Shock	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	10	0
<b>Vascular disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>462</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>195</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>