

**Medicine summary - antipsychotics (to end January 2009) 0-9 year olds**

			Case Group	Death Outcomes	Sole
Case Count			173	8	117
Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	1
		Coagulopathy	1	0	0
		Thrombocytopenia	3	0	1
		Macrocytosis	1	0	1
		Lymphadenitis	1	0	0
		Lymphadenopathy	2	0	0
		Eosinophilia	1	0	1
		Leukopenia	1	0	1
		Agranulocytosis	2	0	1
		Neutropenia	3	0	1
		<b>Blood and lymphatic system disorders</b>		<b>16</b>	<b>0</b>
	Cardiac disorders	Bradycardia	1	0	1
		Cyanosis	2	0	1
		Pulmonary valve stenosis	1	0	1
		Cardiac failure	1	0	1
		Cardiomyopathy	1	0	1
		Myocarditis	1	0	1
		<b>Cardiac disorders</b>		<b>7</b>	<b>0</b>
	Congenital, familial and genetic disorders	Pulmonary valve stenosis congenital	1	0	1
		Haemangioma congenital	1	0	1
		Multiple congenital abnormalities	2	0	2
		Mitochondrial hepatopathy	1	1	1
		Congenital foot malformation	1	0	0
		Congenital hand malformation	1	0	1
		Cryptorchism	1	0	1
		Hypospadias	1	0	1
		<b>Congenital, familial and genetic disorders</b>		<b>9</b>	<b>1</b>
Endocrine disorders	Cushing's syndrome	1	0	1	
	Hyperprolactinaemia	1	0	1	
	<b>Endocrine disorders</b>		<b>2</b>	<b>0</b>	<b>2</b>
Eye disorders	Oculogyric crisis	13	0	5	
	Miosis	1	0	1	
	Eye rolling	1	0	0	
	Photophobia	1	0	1	
	Diplopia	1	0	0	
	<b>Eye disorders</b>		<b>17</b>	<b>0</b>	<b>7</b>
Gastrointestinal disorders	Tooth malformation	1	0	1	
	Tooth discolouration	1	0	1	
	Gingival bleeding	1	0	0	
	Pancreatitis	3	0	3	
	Pancreatitis acute	1	0	1	

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		Case Group	Death Outcomes	Sole	
Reaction Count	Gastrointestinal disorders	Rectal haemorrhage	1	0	1
		Diarrhoea	2	0	1
		Constipation	1	0	1
		Abdominal distension	2	0	2
		Abdominal pain	5	0	4
		Nausea	4	1	2
		Vomiting	8	0	5
		Mouth ulceration	1	0	0
		Stomatitis	1	0	0
		Salivary hypersecretion	2	0	1
		Tongue oedema	1	0	1
		<b>Gastrointestinal disorders</b>	<b>35</b>	<b>1</b>	<b>24</b>
		General disorders and administration site conditions	Hypothermia	2	0
	Pyrexia		9	0	4
	Sudden death		5	5	2
	Sudden infant death syndrome		1	1	1
	Fatigue		4	0	3
	Malaise		2	0	0
	Developmental delay		1	0	0
	Irritability		1	0	1
	Face oedema		3	0	2
	Oedema		3	0	3
	Pain		1	0	1
	Feeling jittery		1	0	0
	Drug ineffective		5	0	3
	Drug withdrawal syndrome		2	0	2
	Drug withdrawal syndrome neonatal		1	0	1
	<b>General disorders and administration site conditions</b>		<b>41</b>	<b>6</b>	<b>25</b>
	Hepatobiliary disorders		Hepatitis cholestatic	1	0
		Hyperbilirubinaemia	1	0	0
		Jaundice	1	1	0
		Hepatic function abnormal	12	1	9
		Hepatic failure	4	4	1
		Hepatosplenomegaly neonatal	1	0	0
		Hepatic necrosis	2	2	1
		Hepatitis	1	0	1
		Hepatocellular injury	2	1	2
		<b>Hepatobiliary disorders</b>	<b>25</b>	<b>9</b>	<b>15</b>
	Infections and infestations	Clostridium difficile colitis	1	0	1
		Vaginal infection	1	0	0
		Sepsis	1	1	0

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Reaction Count	Infections and infestations	Pharyngitis	1	0	1	
		Rhinitis	1	0	0	
		<b>Infections and infestations</b>	<b>5</b>	<b>1</b>	<b>2</b>	
	Injury, poisoning and procedural complications	Drug exposure during pregnancy	5	1	3	
		Overdose	1	0	1	
		<b>Injury, poisoning and procedural complications</b>	<b>6</b>	<b>1</b>	<b>4</b>	
	Investigations	Echocardiogram abnormal	1	0	1	
		Ejection fraction decreased	1	0	1	
		Electrocardiogram abnormal	1	0	1	
		Blood creatine phosphokinase increased	2	0	2	
		Troponin increased	1	0	1	
		Blood amylase increased	2	0	2	
		Lipase increased	1	0	1	
		Carnitine decreased	4	0	2	
		Apgar score abnormal	1	0	1	
		Body temperature increased	1	0	1	
		Weight increased	4	0	4	
		Drug level increased	2	0	2	
		<b>Investigations</b>	<b>21</b>	<b>0</b>	<b>19</b>	
		Metabolism and nutrition disorders	Decreased appetite	7	0	4
			Hypercalcaemia	1	0	1
	Hyperglycaemia		1	0	1	
	Hyperammonaemia		3	0	2	
	<b>Metabolism and nutrition disorders</b>		<b>12</b>	<b>0</b>	<b>8</b>	
	Musculoskeletal and connective tissue disorders	Muscle spasms	1	0	1	
		Muscle twitching	1	0	0	
		Torticollis	1	0	1	
		<b>Musculoskeletal and connective tissue disorders</b>	<b>3</b>	<b>0</b>	<b>2</b>	
	Nervous system disorders	Cerebral haemorrhage neonatal	1	0	0	
		Hypoxic encephalopathy	1	0	1	
		Headache	1	0	1	
		Disturbance in attention	2	0	2	
		Choreoathetosis	1	0	0	
		Dyskinesia	1	0	0	
		Extrapyramidal disorder	4	0	4	
		Hyperkinesia	2	0	2	
		Psychomotor hyperactivity	1	0	1	
		Tardive dyskinesia	1	0	1	
		Dystonia	14	0	12	
		Opisthotonus	2	0	1	

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		Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Tremor	6	0	5
		Ataxia	5	0	3
		Coordination abnormal	1	0	0
		Nystagmus	1	0	0
		Coma	2	1	2
		Consciousness fluctuating	2	0	2
		Lethargy	1	0	1
		Sedation	1	0	1
		Somnolence	10	1	6
		Stupor	1	0	1
		Motor dysfunction	1	0	1
		Dizziness	1	0	0
		Unresponsive to stimuli	1	0	0
		Hyperaesthesia	1	0	1
		Paraesthesia	2	0	2
		Speech disorder	1	0	1
		Visual field defect	2	0	2
		Hypertonia	3	0	1
		Convulsion neonatal	1	0	0
		Grand mal convulsion	2	1	0
		Convulsion	8	0	5
		Epilepsy	1	0	1
			<b>Nervous system disorders</b>	<b>85</b>	<b>3</b>
	Pregnancy, puerperium and perinatal conditions	Foetal growth retardation	1	0	0
		Small for dates baby	1	0	0
		Weight decrease neonatal	1	0	0
			<b>Pregnancy, puerperium and perinatal conditions</b>	<b>3</b>	<b>0</b>
	Psychiatric disorders	Agitation	1	0	0
		Nervousness	4	0	2
		Neurosis	2	0	1
		Learning disorder	1	0	1
		Confusional state	3	0	2
		Delirium	1	0	1
		Depression	1	0	1
		Depersonalisation	2	0	1
		Hallucination	1	0	0
		Hallucination, auditory	1	0	1
		Thinking abnormal	1	0	1
		Affect lability	1	0	0
		Aggression	6	0	4
		Personality disorder	1	0	1

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			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Abnormal behaviour	1	0	1
		Staring	1	0	0
		Mental disorder	1	0	1
		Insomnia	2	0	2
		Nightmare	1	0	1
		Self injurious behaviour	1	0	0
		Suicidal ideation	1	0	0
		<b>Psychiatric disorders</b>	<b>34</b>	<b>0</b>	<b>21</b>
	Renal and urinary disorders	Renal failure acute	1	1	0
		Renal impairment	1	0	1
		Renal tubular necrosis	1	0	1
		Urinary incontinence	5	0	5
		Urinary retention	1	0	0
		Polyuria	1	0	1
		<b>Renal and urinary disorders</b>	<b>10</b>	<b>1</b>	<b>8</b>
	Reproductive system and breast disorders	Breast mass	1	0	0
		Testicular pain	1	0	1
		<b>Reproductive system and breast disorders</b>	<b>2</b>	<b>0</b>	<b>1</b>
	Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	1	0	1
		Infantile apnoeic attack	1	0	0
		Dyspnoea	1	0	1
		Hypoxia	1	0	0
		Epistaxis	2	0	2
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>6</b>	<b>0</b>	<b>4</b>
	Skin and subcutaneous tissue disorders	Urticaria	1	0	1
		Skin striae	1	0	1
		Stevens-Johnson syndrome	1	0	0
		Skin disorder	1	0	0
		Rash erythematous	6	0	2
		Skin exfoliation	1	0	1
		Photosensitivity allergic reaction	1	0	1
		Photosensitivity reaction	1	0	1
		Pruritus	4	0	2
		Rash	7	0	4
		Rash macular	1	0	0
		Rash maculo-papular	4	0	3
		Rash morbilliform	3	0	0
		Alopecia	6	0	5
		Nail discolouration	1	0	0
		Nail disorder	1	0	0
	Purpura	1	0	0	

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Reaction Count	Skin and subcutaneous tissue disorders	<b>Skin and subcutaneous tissue disorders</b>	<b>41</b>	<b>0</b>	<b>21</b>
	Vascular disorders	Hypotension	2	0	1
		Flushing	1	0	0
		Pallor	2	0	0
		<b>Vascular disorders</b>	<b>5</b>	<b>0</b>	<b>1</b>
	<b>Reaction</b>		<b>385</b>	<b>23</b>	<b>245</b>