

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	
		Blood and lymphatic system disorders			16	0
	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	
		Cardiac disorders			7	0
	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	
Congenital, familial and genetic disorders			9	1	8	
Endocrine disorders	Cushing's syndrome	1	0	1		
	Hyperprolactinaemia	1	0	1		
	Endocrine disorders			2	0	2
Eye disorders	Oculogyric crisis	13	0	5		
	Miosis	1	0	1		
	Eye rolling	1	0	0		
	Photophobia	1	0	1		
	Diplopia	1	0	0		
	Eye disorders			17	0	7
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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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
		Gastrointestinal disorders	35	1	24
		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
	General disorders and administration site conditions		41	6	25
	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
		Hepatobiliary disorders	25	9	15
	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	
		Infections and infestations	5	1	2	
	Injury, poisoning and procedural complications	Drug exposure during pregnancy	5	1	3	
		Overdose	1	0	1	
		Injury, poisoning and procedural complications	6	1	4	
	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	
		Investigations	21	0	19	
		Metabolism and nutrition disorders	Decreased appetite	7	0	4
			Hypercalcaemia	1	0	1
	Hyperglycaemia		1	0	1	
	Hyperammonaemia		3	0	2	
	Metabolism and nutrition disorders		12	0	8	
	Musculoskeletal and connective tissue disorders	Muscle spasms	1	0	1	
		Muscle twitching	1	0	0	
		Torticollis	1	0	1	
		Musculoskeletal and connective tissue disorders	3	0	2	
	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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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	
			Nervous system disorders	85	3	60
		Pregnancy, puerperium and perinatal conditions	Foetal growth retardation	1	0	0
	Small for dates baby		1	0	0	
	Weight decrease neonatal		1	0	0	
			Pregnancy, puerperium and perinatal conditions	3	0	0
	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
		Psychiatric disorders	34	0	21
	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
		Renal and urinary disorders	10	1	8
	Reproductive system and breast disorders	Breast mass	1	0	0
		Testicular pain	1	0	1
		Reproductive system and breast disorders	2	0	1
	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
		Respiratory, thoracic and mediastinal disorders	6	0	4
	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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			Case Group	Death Outcomes	Sole
Reaction Count	Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	41	0	21
	Vascular disorders	Hypotension	2	0	1
		Flushing	1	0	0
		Pallor	2	0	0
		Vascular disorders	5	0	1
	Reaction			385	23