

Medicine summary - ADHDs (to end August 2009)

			Case Group	Death Outcomes	Sole
Case Count			317	3	243
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	0	1
		Aplastic anaemia	1	0	1
		Pancytopenia	1	0	1
		Coagulopathy	1	0	0
		Neutropenia	1	0	0
		Blood and lymphatic system disorders	6	0	3
	Cardiac disorders	Arrhythmia	1	0	1
		Tachycardia	12	0	8
		Sinus tachycardia	1	0	1
		Supraventricular tachycardia	1	0	1
		Cardiac arrest	1	0	1
		Ventricular extrasystoles	1	0	1
		Ventricular fibrillation	1	0	1
		Palpitations	8	0	5
		Myocardial infarction	1	0	0
		Cardiomyopathy	2	0	2
		Cardiac disorders	29	0	21
		Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0
	Tourette's disorder		2	0	2
	Congenital, familial and genetic disorders		3	0	3
	Ear and labyrinth disorders	Hearing impaired	1	0	1
		Tinnitus	1	0	1
		Ear and labyrinth disorders	2	0	2
	Endocrine disorders	Hypothyroidism	1	0	1
		Endocrine disorders	1	0	1
	Eye disorders	Eye oedema	1	0	1
		Eye pain	1	0	0
Lens disorder		1	0	1	
Conjunctivitis		1	0	0	
Blepharospasm		1	0	1	
Eyelid ptosis		1	0	1	
Eye movement disorder		1	0	1	
Oculogyric crisis		2	0	2	
Strabismus		1	0	1	
Mydriasis		2	0	0	
Photophobia		4	0	2	
Optic atrophy		1	0	1	
Retinal pigmentation		1	0	0	
Accommodation disorder		1	0	1	
Vision blurred		5	0	4	
Visual impairment		3	0	3	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Eye disorders	Eye disorders	27	0	19	
	Gastrointestinal disorders	Tooth discolouration	1	0	1	
		Gingival hyperplasia	2	0	1	
		Pancreatitis	3	0	3	
		Gastrointestinal disorder	2	0	2	
		Gastrointestinal inflammation	1	0	1	
		Diarrhoea	6	0	4	
		Gastrooesophageal reflux disease	1	0	0	
		Dyspepsia	1	0	1	
		Abdominal pain	8	0	7	
		Abdominal pain upper	5	0	5	
		Abdominal discomfort	1	0	1	
		Faecal incontinence	1	0	1	
		Nausea	16	1	13	
		Vomiting	12	1	11	
		Duodenal scarring	1	0	1	
		Chapped lips	1	0	1	
		Cheilitis	1	0	1	
		Lip swelling	2	0	1	
		Mouth ulceration	1	0	0	
		Stomatitis	1	0	1	
		Dry mouth	4	0	4	
			Gastrointestinal disorders	71	2	60
		General disorders and administration site conditions	Pyrexia	2	0	1
			Sudden death	2	2	1
			Asthenia	2	0	0
			Fatigue	8	0	5
	Malaise		2	0	2	
	Abasia		2	0	1	
	Condition aggravated		2	0	1	
	Exercise tolerance decreased		1	0	1	
	Influenza like illness		1	0	1	
	Irritability		4	0	4	
Swelling	1		0	1		
Face oedema	2		0	1		
Oedema peripheral	1		0	0		
Chest pain	6		0	4		
Pain	5		0	5		
Chest discomfort	2		0	2		
Chills	3		0	1		
Feeling abnormal	3	0	3			
Feeling cold	2	0	2			

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			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	Feeling hot	1	0	0
		Drug interaction	4	0	0
		Drug effect decreased	3	0	2
		Drug ineffective	17	0	13
		Paradoxical drug reaction	1	0	0
		Therapeutic response decreased	2	0	1
		Drug withdrawal syndrome	1	0	1
		Mass	1	0	1
		Product quality issue	1	0	1
		General disorders and administration site conditions	82	2	55
	Hepatobiliary disorders	Hepatitis	1	0	1
		Hepatobiliary disorders	1	0	1
	Immune system disorders	Anaphylactic shock	1	0	1
		Immune system disorders	1	0	1
	Infections and infestations	Otitis media	1	0	0
		Infection	2	0	2
		Orchitis	1	0	1
		Pharyngitis	2	0	0
		Rhinitis	1	0	0
		Cystitis	1	0	1
		Viral infection	1	0	0
		Pancreatitis viral	1	0	1
		Infections and infestations	10	0	5
		Injury, poisoning and procedural complications	Fall	2	0
	Contusion		1	0	1
	Wrong drug administered		1	0	0
	Overdose		2	0	2
	Injury, poisoning and procedural complications		6	0	4
	Investigations	Electrocardiogram abnormal	2	0	1
		Heart rate increased	4	0	3
		Heart rate irregular	1	0	0
		Blood pressure increased	2	0	2
		Androgens increased	1	0	1
		Bleeding time prolonged	1	0	0
		Prothrombin level decreased	1	0	0
		Neutrophil count increased	1	0	1
		Electroencephalogram abnormal	1	0	0
		Corneal reflex decreased	1	0	1
		Intraocular pressure increased	1	0	1
		Visual acuity tests abnormal	1	0	1
		Weight decreased	10	0	9

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Reaction Count	Investigations	Weight increased	2	0	2
		Investigations	29	0	22
	Metabolism and nutrition disorders	Anorexia	13	0	11
		Decreased appetite	2	0	2
		Increased appetite	2	0	2
		Obesity	2	0	2
		Polydipsia	2	0	2
		Hyponatraemia	1	0	0
		Hypoglycaemia	1	0	0
		Metabolism and nutrition disorders	23	0	19
	Musculoskeletal and connective tissue disorders	Pain in jaw	1	0	1
		Arthralgia	1	0	1
		Joint swelling	1	0	1
		Myalgia	3	0	2
		Muscle spasms	2	0	1
		Muscle twitching	11	0	8
		Muscle rigidity	3	0	1
		Growth retardation	3	0	2
		Sensation of heaviness	1	0	1
		Back pain	1	0	1
		Musculoskeletal and connective tissue disorders	27	0	19
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	1	0	0
		Neoplasm malignant	1	0	1
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0	1
	Nervous system disorders	Subarachnoid haemorrhage	1	0	1
		Facial spasm	1	0	1
		Optic neuritis	1	0	1
		Headache	20	0	15
		Migraine	1	0	1
		Migraine with aura	1	0	1
		Intracranial pressure increased	1	0	1
		Dementia	1	0	1
		Amnesia	2	0	2
Disturbance in attention		4	0	4	
Judgement impaired		1	0	1	
Choreoathetosis		1	0	1	
Dyskinesia		10	0	7	
Extrapyramidal disorder		2	0	1	
Hyperkinesia		6	0	2	
Psychomotor hyperactivity	2	0	2		

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Reaction Count	Nervous system disorders	Tardive dyskinesia	1	0	1	
		Dystonia	8	0	4	
		Tremor	11	0	9	
		Hyperreflexia	2	0	0	
		Hyporeflexia	1	0	0	
		Ataxia	1	0	0	
		Nystagmus	1	0	0	
		Coma	1	0	0	
		Dysgraphia	1	0	1	
		Lethargy	3	0	2	
		Loss of consciousness	1	0	0	
		Somnolence	8	0	5	
		Syncope	2	0	2	
		Motor dysfunction	1	0	1	
		Clonus	1	0	0	
		Dizziness	8	0	6	
		Myoclonus	1	0	0	
		Crying	5	0	5	
		Burning sensation mucosal	1	0	1	
		Formication	1	0	0	
		Hyperaesthesia	2	0	1	
		Paraesthesia	3	0	2	
		Dysgeusia	2	0	2	
		Hypoaesthesia	2	0	2	
		Neuralgia	1	0	0	
		Dysarthria	2	0	1	
		Speech disorder	1	0	0	
		Visual field defect	1	0	1	
		Hypertonia	5	0	1	
		Hypotonia	1	0	0	
		Neuroleptic malignant syndrome	1	0	1	
		Serotonin syndrome	1	0	0	
		Muscle contractions involuntary	1	0	0	
		Convulsion	7	0	0	
		Poor quality sleep	1	0	0	
			Nervous system disorders	145	0	90
		Pregnancy, puerperium and perinatal conditions	Neonatal disorder	1	0	1
			Pregnancy, puerperium and perinatal conditions	1	0	1
		Psychiatric disorders	Agitation	19	0	14
			Anxiety	14	0	10
			Nervousness	8	0	6

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Reaction Count	Psychiatric disorders		Case Group	Death Outcomes	Sole
		Fear	2	0	2
		Panic attack	2	0	2
		Neurosis	5	0	3
		Obsessive thoughts	2	0	2
		Obsessive-compulsive disorder	4	0	2
		Restlessness	3	0	2
		Head banging	1	0	1
		Tic	9	0	9
		Distractibility	1	0	0
		Logorrhoea	1	0	1
		Lack of spontaneous speech	1	0	1
		Confusional state	7	1	4
		Disorientation	2	0	2
		Paramnesia	1	0	1
		Depression	15	0	14
		Major depression	1	0	1
		Depressed mood	5	0	4
		Tearfulness	2	0	2
		Delusion	3	0	3
		Hallucination	10	1	7
		Hallucination, auditory	7	0	7
		Hallucination, visual	2	0	2
		Thinking abnormal	3	0	3
		Impulsive behaviour	2	0	2
		Mania	1	0	1
		Affect lability	7	0	7
		Inappropriate affect	1	0	0
		Anger	8	0	8
		Emotional disorder	2	0	2
		Emotional distress	1	0	1
		Mood altered	2	0	2
		Mood swings	7	0	7
		Apathy	2	0	1
		Aggression	21	0	20
		Asocial behaviour	1	0	1
		Attention-seeking behaviour	1	0	1
		Disturbance in social behaviour	1	0	1
		Homicidal ideation	3	0	2
		Hostility	1	0	1
		Paranoia	6	0	6
		Social avoidant behaviour	4	0	4
		Abnormal behaviour	10	0	10

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Reaction Count	Psychiatric disorders	Regressive behaviour	1	0	1
		Neglect of personal appearance	1	0	1
		Psychiatric symptom	1	0	1
		Mental disorder	1	0	1
		Alcohol abuse	1	0	0
		Drug abuse	1	0	0
		Drug dependence	1	0	1
		Intentional drug misuse	1	0	1
		Withdrawal syndrome	4	0	3
		Psychotic behaviour	2	0	2
		Psychotic disorder	9	0	8
		Insomnia	10	0	10
		Abnormal sleep-related event	1	0	0
		Nightmare	1	0	1
		Sleep disorder	2	0	2
		Intentional self-injury	5	0	4
		Self injurious behaviour	4	0	4
		Self-injurious ideation	1	0	1
		Suicidal ideation	30	0	24
		Suicide attempt	6	0	6
	Psychiatric disorders	294	2	253	
Renal and urinary disorders	Renal failure acute	1	1	1	
	Pollakiuria	1	0	1	
	Urinary incontinence	1	0	1	
	Urinary retention	1	0	1	
	Haematuria	1	0	1	
	Polyuria	2	0	2	
	Renal pain	1	0	1	
		Renal and urinary disorders	8	1	8
Reproductive system and breast disorders	Breast swelling	1	0	1	
	Balanitis	1	0	1	
	Testicular disorder	1	0	0	
		Reproductive system and breast disorders	3	0	2
Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	0	1	
	Wheezing	2	0	2	
	Pulmonary embolism	1	0	1	
	Dyspnoea	7	0	4	
	Hyperventilation	1	0	0	
	Cough	2	0	1	
	Oropharyngeal pain	1	0	1	
	Throat tightness	1	0	1	
	Stridor	1	0	0	

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Reaction Count	Respiratory, thoracic and mediastinal disorders	Epistaxis	1	0	1
		Respiratory, thoracic and mediastinal disorders	18	0	12
	Skin and subcutaneous tissue disorders	Angioedema	3	0	2
		Periorbital oedema	2	0	2
		Urticaria	4	0	4
		Erythema multiforme	1	0	0
		Stevens-Johnson syndrome	1	0	0
		Skin lesion	1	0	1
		Swelling face	1	0	0
		Erythema	1	0	1
		Rash erythematous	3	0	1
		Pruritus	6	0	5
		Rash	8	0	7
		Rash maculo-papular	1	0	0
		Skin ulcer	1	0	1
		Alopecia	5	0	4
		Cold sweat	2	0	2
		Hyperhidrosis	12	0	9
		Night sweats	1	0	1
		Nail discolouration	1	0	1
		Henoch-Schonlein purpura	1	0	1
		Purpura	1	0	1
	Skin and subcutaneous tissue disorders	56	0	43	
	Social circumstances	Physical assault	1	0	1
		Sexual abuse	1	0	0
		Educational problem	1	0	1
		Social circumstances	3	0	2
	Surgical and medical procedures	Therapy regimen changed	3	0	2
		Surgical and medical procedures	3	0	2
	Vascular disorders	Peripheral ischaemia	2	0	2
		Raynaud's phenomenon	1	0	1
		Hypotension	1	0	1
		Orthostatic hypotension	1	0	1
Flushing		2	0	2	
Pallor		3	0	1	
Hypertension		2	0	1	
Vascular disorders		12	0	9	
Reaction			863	7	658