

Medicine summary six ADHD drugs to 8 April 2011

			Case Group	Death Outcomes	Sole
Case Count			337	4	254
Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	1
		Aplastic anaemia	1	0	1
		Pancytopenia	1	0	1
		Coagulopathy	1	0	0
		Neutropenia	1	0	0
		Blood and lymphatic system disorders	5	0	3
	Cardiac disorders	Tachycardia	9	0	5
		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
		Cyanosis	1	0	0
		Palpitations	6	0	4
		Myocardial infarction	1	0	0
		Cardiomyopathy	3	0	3
		Cardiac disorders	25	0	17
		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
	Eye disorders	Eye oedema	1	0	1
		Eye pain	1	0	0
		Lens disorder	1	0	1
		Periorbital oedema	1	0	1
Conjunctivitis		1	0	0	
Blepharospasm		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		2	0	2	
Eye disorders		26	0	18	
Gastrointestinal disorders		Tooth discolouration	1	0	1

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Reaction Count	Gastrointestinal disorders	Gingival hyperplasia	2	0	1
		Pancreatitis	4	0	4
		Gastrointestinal disorder	1	0	1
		Gastrointestinal inflammation	1	0	1
		Diarrhoea	4	0	2
		Gastrooesophageal reflux disease	1	0	0
		Dyspepsia	1	0	1
		Abdominal pain	9	0	8
		Abdominal pain upper	7	0	7
		Abdominal discomfort	1	0	1
		Faecal incontinence	1	0	1
		Nausea	15	1	12
		Vomiting	9	1	8
		Duodenal scarring	1	0	1
		Coeliac disease	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	3	0	3	
	Gastrointestinal disorders		68	2	57
	General disorders and administration site conditions	Hypothermia	3	0	0
		Pyrexia	2	0	1
		Sudden death	2	2	1
		Asthenia	2	0	0
		Fatigue	6	0	4
Malaise		2	0	2	
Abasia		2	0	1	
Condition aggravated		3	0	2	
Exercise tolerance decreased		1	0	1	
Influenza like illness		1	0	1	
Irritability		3	0	3	
Swelling		1	0	1	
Face oedema		2	0	1	
Oedema peripheral		1	0	0	
Chest pain		7	0	5	
Pain		4	0	4	
Chest discomfort		2	0	2	
Chills	3	0	1		
Feeling abnormal	3	0	3		
Feeling cold	1	0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	Feeling hot	1	0	0
		Drug interaction	6	0	0
		Drug effect decreased	3	0	2
		Drug ineffective	14	0	10
		Paradoxical drug reaction	1	0	0
		Therapeutic response decreased	2	0	1
		Mass	1	0	1
		Medication residue	1	0	1
		Product quality issue	1	0	1
			General disorders and administration site conditions	81	2
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	Helicobacter infection	1	0	1	
	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	11	0	6
Injury, poisoning and procedural complications	Accident	1	0	1	
	Fall	3	0	1	
	Road traffic accident	1	0	1	
	Contusion	1	0	1	
	Wrong drug administered	1	0	0	
	Intentional overdose	1	0	1	
	Overdose	2	0	2	
		Injury, poisoning and procedural complications	10	0	7
Investigations	Ejection fraction decreased	1	0	1	
	Electrocardiogram QT prolonged	1	0	1	
	Electrocardiogram abnormal	1	0	0	
	Heart rate increased	3	0	2	
	Blood pressure increased	3	0	3	
	Androgens increased	1	0	1	
	Bleeding time prolonged	1	0	0	
	Prothrombin level decreased	1	0	0	
	Neutrophil count increased	1	0	1	

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Reaction Count	Investigations	Liver function test abnormal	1	0	1
		Electroencephalogram abnormal	1	0	0
		Corneal reflex decreased	1	0	1
		Visual acuity tests abnormal	1	0	1
		Weight decreased	11	0	10
		Weight increased	2	0	2
		Investigations	30	0	24
	Metabolism and nutrition disorders	Decreased appetite	15	0	13
		Increased appetite	1	0	1
		Polydipsia	2	0	2
		Hyponatraemia	2	0	0
		Type 1 diabetes mellitus	1	0	1
		Hypoglycaemia	1	0	0
		Metabolism and nutrition disorders	22	0	17
	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	10	0	7
		Muscle rigidity	3	0	1
		Growth retardation	2	0	2
		Back pain	1	0	1
		Musculoskeletal and connective tissue disorders	24	0	17
	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	Cerebrovascular accident	1	0	1
		Subarachnoid haemorrhage	1	0	1
		Facial spasm	1	0	1
		Optic neuritis	1	0	1
		Headache	16	0	11
		Migraine	1	0	1
		Migraine with aura	2	0	2
		Intracranial pressure increased	1	0	1
		Dementia	1	0	1
		Amnesia	3	0	2
		Disturbance in attention	6	0	6
		Judgement impaired	1	0	1
		Dyskinesia	10	0	7

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			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Extrapyramidal disorder	2	0	1
		Hyperkinesia	6	0	2
		Psychomotor hyperactivity	1	0	1
		Tardive dyskinesia	2	0	2
		Dystonia	8	0	4
		Tremor	10	0	8
		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	2	0	2
		Loss of consciousness	1	0	0
		Somnolence	9	0	7
		Syncope	2	0	2
		Motor dysfunction	1	0	1
		Clonus	1	0	0
		Dizziness	8	0	5
		Myoclonus	1	0	0
		Unresponsive to stimuli	2	0	2
		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	2	0	0
		Muscle contractions involuntary	1	0	0
		Dreamy state	1	0	0
		Convulsion	9	0	2
		Sleep paralysis	1	0	1
Poor quality sleep	1	0	0		
Nervous system disorders			151	0	94

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			Case Group	Death Outcomes	Sole
Reaction Count	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	12	0	9
		Nervousness	8	0	6
		Fear	2	0	2
		Panic attack	1	0	1
		Neurosis	5	0	3
		Obsessive thoughts	2	0	2
		Obsessive-compulsive disorder	5	0	3
		Restlessness	3	0	2
		Head banging	1	0	1
		Tic	7	0	7
		Distractibility	1	0	0
		Logorrhoea	1	0	1
		Screaming	1	0	1
		Confusional state	7	1	4
		Disorientation	2	0	2
		Paramnesia	1	0	1
		Depression	14	0	13
		Major depression	1	0	1
		Anhedonia	1	0	1
		Depressed mood	6	0	5
		Tearfulness	1	0	1
		Delusion	3	0	3
		Hallucination	10	1	7
		Hallucination, auditory	6	0	6
		Hallucination, visual	1	0	1
		Thinking abnormal	4	0	4
		Impulsive behaviour	2	0	2
		Mania	1	0	1
		Affect lability	4	0	4
		Inappropriate affect	1	0	0
		Anger	7	0	7
		Emotional disorder	2	0	2
Emotional distress	1	0	1		
Mood altered	1	0	1		
Mood swings	8	0	8		
Apathy	2	0	1		
Aggression	24	0	23		
Asocial behaviour	1	0	1		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Psychiatric disorders	Attention-seeking behaviour	1	0	1	
		Disturbance in social behaviour	2	0	2	
		Homicidal ideation	3	0	2	
		Hostility	1	0	1	
		Paranoia	7	0	7	
		Social avoidant behaviour	4	0	4	
		Violence-related symptom	1	0	1	
		Abnormal behaviour	14	0	13	
		Regressive behaviour	1	0	1	
		Neglect of personal appearance	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	12	0	9	
		Insomnia	10	0	10	
		Abnormal sleep-related event	1	0	0	
		Nightmare	1	0	1	
		Sleep terror	1	0	1	
		Sleep disorder	2	0	2	
		Completed suicide	1	1	1	
		Intentional self-injury	5	0	4	
		Self injurious behaviour	7	0	6	
		Self-injurious ideation	1	0	1	
		Suicidal behaviour	1	0	1	
		Suicidal ideation	39	0	31	
		Suicide attempt	8	0	8	
			Psychiatric disorders	314	3	268
		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	Amenorrhoea	1	0	1		
	Erectile dysfunction	1	0	1		
	Testicular disorder	1	0	0		

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			Case Group	Death Outcomes	Sole
Reaction Count	Reproductive system and breast disorders	Reproductive system and breast disorders	3	0	2
	Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	0	1
		Wheezing	1	0	1
		Pulmonary embolism	1	0	1
		Dyspnoea	7	0	4
		Hyperventilation	1	0	0
		Cough	2	0	1
		Oropharyngeal pain	1	0	1
		Stridor	1	0	0
		Respiratory, thoracic and mediastinal disorders	15	0	9
	Skin and subcutaneous tissue disorders	Angioedema	3	0	2
		Urticaria	2	0	2
		Erythema multiforme	1	0	0
		Stevens-Johnson syndrome	1	0	0
		Skin lesion	1	0	1
		Swelling face	1	0	0
		Yellow skin	1	0	1
		Erythema	1	0	1
		Rash erythematous	3	0	1
		Pruritus	5	0	5
		Rash	7	0	6
		Rash maculo-papular	1	0	0
		Skin ulcer	1	0	1
		Alopecia	5	0	4
		Cold sweat	1	0	1
		Hyperhidrosis	10	0	7
		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	48	0	36	
	Social circumstances	Loss of employment	1	0	0
		Physical assault	1	0	1
		Sexual abuse	1	0	0
		Educational problem	1	0	1
		Social circumstances	4	0	2
	Surgical and medical procedures	Off label use	1	0	1
		Therapy regimen changed	1	0	0
		Surgical and medical procedures	2	0	1
	Vascular disorders	Peripheral ischaemia	2	0	2
		Raynaud's phenomenon	3	0	1
		Peripheral coldness	1	0	0

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Reaction Count	Vascular disorders	Hypotension	1	0	1
		Orthostatic hypotension	2	0	1
		Flushing	2	0	2
		Pallor	2	0	0
		Hypertension	2	0	1
		Vascular disorders	15	0	8
Reaction			872	8	653