

Medicine summary Ritalin to 8 April 2011

			Case Group	Death Outcomes	Sole
Case Count			136	4	102
Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	1
		Aplastic anaemia	1	0	1
		Pancytopenia	1	0	1
		Blood and lymphatic system disorders	3	0	3
	Cardiac disorders	Tachycardia	3	0	3
		Cardiac arrest	1	0	1
		Ventricular fibrillation	1	0	1
		Cyanosis	1	0	0
		Palpitations	3	0	2
		Myocardial infarction	1	0	0
		Cardiomyopathy	1	0	1
		Cardiac disorders	11	0	8
	Congenital, familial and genetic disorders	Tourette's disorder	1	0	1
		Congenital, familial and genetic disorders	1	0	1
	Eye disorders	Eye oedema	1	0	1
		Eye pain	1	0	0
		Conjunctivitis	1	0	0
		Blepharospasm	1	0	1
		Eye movement disorder	1	0	1
		Oculogyric crisis	2	0	2
		Photophobia	1	0	0
		Optic atrophy	1	0	1
		Retinal pigmentation	1	0	0
		Vision blurred	4	0	3
		Visual impairment	1	0	1
		Eye disorders	15	0	10
		Gastrointestinal disorders	Tooth discolouration	1	0
	Gingival hyperplasia		2	0	1
	Pancreatitis		2	0	2
	Diarrhoea		4	0	2
	Abdominal pain		3	0	2
	Abdominal pain upper		3	0	3
	Abdominal discomfort		1	0	1
Nausea	7		1	6	
Vomiting	3		1	3	
Duodenal scarring	1		0	1	
Chapped lips	1		0	1	
Lip swelling	2		0	1	
Mouth ulceration	1		0	0	
Gastrointestinal disorders	31		2	24	

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			Case Group	Death Outcomes	Sole	
Reaction Count	General disorders and administration site conditions	Hypothermia	3	0	0	
		Pyrexia	2	0	1	
		Sudden death	2	2	1	
		Fatigue	4	0	2	
		Malaise	1	0	1	
		Influenza like illness	1	0	1	
		Irritability	1	0	1	
		Swelling	1	0	1	
		Face oedema	1	0	0	
		Oedema peripheral	1	0	0	
		Chest pain	4	0	2	
		Pain	1	0	1	
		Chest discomfort	1	0	1	
		Feeling abnormal	3	0	3	
		Drug interaction	2	0	0	
		Drug effect decreased	2	0	1	
		Drug ineffective	6	0	4	
		Mass	1	0	1	
			General disorders and administration site conditions	37	2	21
		Infections and infestations		Helicobacter infection	1	0
Otitis media	1			0	0	
Infection	2			0	2	
Pharyngitis	2			0	0	
Rhinitis	1			0	0	
Viral infection	1			0	0	
Infections and infestations	8			0	3	
Injury, poisoning and procedural complications		Accident	1	0	1	
		Fall	1	0	0	
		Road traffic accident	1	0	1	
		Injury, poisoning and procedural complications	3	0	2	
Investigations		Ejection fraction decreased	1	0	1	
		Electrocardiogram abnormal	1	0	0	
		Heart rate increased	2	0	1	
		Blood pressure increased	1	0	1	
		Androgens increased	1	0	1	
		Prothrombin level decreased	1	0	0	
		Weight decreased	5	0	4	
		Investigations	12	0	8	
Metabolism and nutrition disorders		Decreased appetite	6	0	5	
		Polydipsia	1	0	1	
		Type 1 diabetes mellitus	1	0	1	

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Reaction Count	Metabolism and nutrition disorders	Metabolism and nutrition disorders	8	0	7
	Musculoskeletal and connective tissue disorders	Pain in jaw	1	0	1
		Myalgia	2	0	2
		Muscle spasms	1	0	1
		Muscle twitching	4	0	3
		Growth retardation	2	0	2
		Musculoskeletal and connective tissue disorders	10	0	9
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	1	0
	Neoplasm malignant		1	0	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		2	0	1
	Nervous system disorders	Optic neuritis	1	0	1
		Headache	6	0	3
		Migraine with aura	1	0	1
		Dementia	1	0	1
		Amnesia	2	0	2
		Disturbance in attention	1	0	1
		Dyskinesia	5	0	4
		Extrapyramidal disorder	1	0	1
		Hyperkinesia	2	0	2
		Psychomotor hyperactivity	1	0	1
		Tardive dyskinesia	1	0	1
		Dystonia	3	0	3
		Tremor	3	0	2
		Ataxia	1	0	0
		Coma	1	0	0
		Lethargy	1	0	1
		Somnolence	8	0	6
		Dizziness	2	0	0
		Unresponsive to stimuli	2	0	2
		Crying	2	0	2
		Formication	1	0	0
		Dysgeusia	1	0	1
		Visual field defect	1	0	1
Hypertonia		1	0	1	
Neuroleptic malignant syndrome		1	0	1	
Convulsion		1	0	0	
Poor quality sleep		1	0	0	
Nervous system disorders		52	0	38	
Psychiatric disorders	Agitation	3	0	1	
	Anxiety	3	0	2	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Psychiatric disorders	Nervousness	4	0	4	
		Neurosis	4	0	3	
		Obsessive thoughts	1	0	1	
		Obsessive-compulsive disorder	1	0	0	
		Restlessness	1	0	0	
		Tic	2	0	2	
		Distractibility	1	0	0	
		Screaming	1	0	1	
		Confusional state	5	1	3	
		Disorientation	1	0	1	
		Depression	7	0	6	
		Depressed mood	1	0	1	
		Tearfulness	1	0	1	
		Hallucination	5	1	4	
		Thinking abnormal	1	0	1	
		Mania	1	0	1	
		Inappropriate affect	1	0	0	
		Mood swings	1	0	1	
		Apathy	1	0	0	
		Aggression	6	0	6	
		Asocial behaviour	1	0	1	
		Disturbance in social behaviour	1	0	1	
		Paranoia	2	0	2	
		Social avoidant behaviour	1	0	1	
		Abnormal behaviour	2	0	2	
		Alcohol abuse	1	0	0	
		Drug abuse	1	0	0	
		Drug dependence	1	0	1	
		Withdrawal syndrome	2	0	1	
		Psychotic disorder	4	0	4	
		Insomnia	3	0	3	
		Abnormal sleep-related event	1	0	0	
		Nightmare	1	0	1	
		Sleep terror	1	0	1	
		Sleep disorder	1	0	1	
		Completed suicide	1	1	1	
		Suicidal ideation	4	0	3	
		Suicide attempt	5	0	5	
			Psychiatric disorders	85	3	67
			Renal and urinary disorders			
			Renal failure acute	1	1	1
			Pollakiuria	1	0	1
		Polyuria	1	0	1	

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			Case Group	Death Outcomes	Sole
Reaction Count	Renal and urinary disorders	Renal and urinary disorders	3	1	3
	Reproductive system and breast disorders	Erectile dysfunction	1	0	1
		Reproductive system and breast disorders	1	0	1
	Respiratory, thoracic and mediastinal disorders	Dyspnoea	3	0	1
		Cough	1	0	0
		Oropharyngeal pain	1	0	1
		Stridor	1	0	0
		Respiratory, thoracic and mediastinal disorders	6	0	2
	Skin and subcutaneous tissue disorders	Angioedema	2	0	1
		Urticaria	1	0	1
		Erythema multiforme	1	0	0
		Stevens-Johnson syndrome	1	0	0
		Swelling face	1	0	0
		Yellow skin	1	0	1
		Rash erythematous	1	0	0
		Pruritus	2	0	2
		Rash	4	0	3
		Rash maculo-papular	1	0	0
		Alopecia	4	0	4
		Cold sweat	1	0	1
		Hyperhidrosis	4	0	3
		Skin and subcutaneous tissue disorders	24	0	16
		Social circumstances	Physical assault	1	0
	Sexual abuse		1	0	0
	Social circumstances		2	0	1
	Surgical and medical procedures	Off label use	1	0	1
		Surgical and medical procedures	1	0	1
	Vascular disorders	Peripheral ischaemia	1	0	1
		Raynaud's phenomenon	1	0	0
		Peripheral coldness	1	0	0
		Hypotension	1	0	1
		Flushing	1	0	1
		Pallor	2	0	0
Hypertension		1	0	0	
Vascular disorders	8	0	3		
Reaction			323	8	229