

Medicine summary - Ritalin (incl LA) (to end August 2009)

			Case Group	Death Outcomes	Sole
Case Count			144	3	112
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	0	1
		Aplastic anaemia	1	0	1
		Pancytopenia	1	0	1
		Blood and lymphatic system disorders	4	0	3
	Cardiac disorders	Arrhythmia	1	0	1
		Tachycardia	5	0	5
		Cardiac arrest	1	0	1
		Ventricular fibrillation	1	0	1
		Palpitations	5	0	3
		Myocardial infarction	1	0	0
		Cardiomyopathy	1	0	1
		Cardiac disorders	15	0	12
	Congenital, familial and genetic disorders	Tourette's disorder	1	0	1
		Congenital, familial and genetic disorders	1	0	1
	Endocrine disorders	Hypothyroidism	1	0	1
		Endocrine 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	2	0	2
		Eye disorders	16	0	11
	Gastrointestinal disorders	Tooth discolouration	1	0	1
		Gingival hyperplasia	2	0	1
		Pancreatitis	2	0	2
		Diarrhoea	5	0	3
		Abdominal pain	3	0	2
Abdominal pain upper		2	0	2	
Abdominal discomfort		1	0	1	
Nausea		9	1	8	
Vomiting		5	1	5	
Duodenal scarring		1	0	1	
Chapped lips		1	0	1	
Lip swelling		2	0	1	
Mouth ulceration		1	0	0	

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Reaction Count	Gastrointestinal disorders	Dry mouth	1	0	1
		Gastrointestinal disorders	36	2	29
	General disorders and administration site conditions	Pyrexia	2	0	1
		Sudden death	2	2	1
		Fatigue	6	0	3
		Malaise	2	0	2
		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	3	0	1
		Pain	2	0	2
		Chest discomfort	1	0	1
		Feeling abnormal	3	0	3
		Drug interaction	2	0	0
		Drug effect decreased	2	0	1
		Drug ineffective	9	0	7
		Drug withdrawal syndrome	1	0	1
		Mass	1	0	1
		Product quality issue	1	0	1
		General disorders and administration site conditions	42	2	28
	Infections and infestations	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	7	0	2
	Injury, poisoning and procedural complications	Fall	1	0	0
		Injury, poisoning and procedural complications	1	0	0
	Investigations	Electrocardiogram abnormal	2	0	1
		Heart rate increased	3	0	2
		Heart rate irregular	1	0	0
		Androgens increased	1	0	1
		Prothrombin level decreased	1	0	0
		Intraocular pressure increased	1	0	1
		Weight decreased	5	0	4
		Weight increased	1	0	1
		Investigations	15	0	10
	Metabolism and nutrition disorders	Anorexia	6	0	5
		Decreased appetite	1	0	1

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Reaction Count	Metabolism and nutrition disorders	Increased appetite	1	0	1
		Obesity	2	0	2
		Polydipsia	1	0	1
		Metabolism and nutrition disorders	11	0	10
	Musculoskeletal and connective tissue disorders	Pain in jaw	1	0	1
		Myalgia	2	0	2
		Muscle spasms	1	0	1
		Muscle twitching	5	0	4
		Growth retardation	2	0	2
		Sensation of heaviness	1	0	1
		Musculoskeletal and connective tissue disorders	12	0	11
	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	Optic neuritis	1	0	1
		Headache	10	0	7
		Dementia	1	0	1
		Amnesia	2	0	2
		Choreoathetosis	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	4	0	3
		Ataxia	1	0	0
		Coma	1	0	0
		Lethargy	2	0	1
		Somnolence	7	0	4
		Dizziness	3	0	1
		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	55	0	39		

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Reaction Count	Psychiatric disorders	Agitation	4	0	2
		Anxiety	6	0	4
		Nervousness	4	0	4
		Panic attack	1	0	1
		Neurosis	4	0	3
		Obsessive thoughts	1	0	1
		Obsessive-compulsive disorder	1	0	0
		Restlessness	1	0	0
		Tic	3	0	3
		Distractibility	1	0	0
		Lack of spontaneous speech	1	0	1
		Confusional state	5	1	3
		Disorientation	1	0	1
		Depression	10	0	9
		Tearfulness	1	0	1
		Hallucination	6	1	5
		Hallucination, visual	1	0	1
		Thinking abnormal	1	0	1
		Mania	1	0	1
		Affect lability	2	0	2
		Inappropriate affect	1	0	0
		Anger	1	0	1
		Mood altered	1	0	1
		Apathy	1	0	0
		Aggression	5	0	5
		Asocial behaviour	1	0	1
		Paranoia	2	0	2
		Social avoidant behaviour	1	0	1
		Abnormal behaviour	2	0	2
		Psychiatric symptom	1	0	1
		Alcohol abuse	1	0	0
		Drug abuse	1	0	0
		Drug dependence	1	0	1
		Withdrawal syndrome	3	0	2
		Psychotic disorder	3	0	3
		Insomnia	3	0	3
		Abnormal sleep-related event	1	0	0
		Nightmare	1	0	1
		Sleep disorder	1	0	1
		Intentional self-injury	1	0	1
Suicidal ideation	4	0	3		
Suicide attempt	4	0	4		

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Reaction Count	Psychiatric disorders	Psychiatric disorders	95	2	76
	Renal and urinary disorders	Renal failure acute	1	1	1
		Pollakiuria	1	0	1
		Polyuria	1	0	1
		Renal and urinary disorders	3	1	3
	Respiratory, thoracic and mediastinal disorders	Wheezing	1	0	1
		Dyspnoea	3	0	1
		Cough	1	0	0
		Oropharyngeal pain	1	0	1
		Stridor	1	0	0
		Epistaxis	1	0	1
		Respiratory, thoracic and mediastinal disorders	8	0	4
	Skin and subcutaneous tissue disorders	Angioedema	2	0	1
		Urticaria	3	0	3
		Erythema multiforme	1	0	0
		Stevens-Johnson syndrome	1	0	0
		Swelling face	1	0	0
		Rash erythematous	1	0	0
		Pruritus	3	0	2
		Rash	4	0	3
		Rash maculo-papular	1	0	0
		Alopecia	4	0	4
		Cold sweat	2	0	2
		Hyperhidrosis	6	0	5
		Skin and subcutaneous tissue disorders	29	0	20
	Social circumstances	Physical assault	1	0	1
		Sexual abuse	1	0	0
		Social circumstances	2	0	1
	Surgical and medical procedures	Therapy regimen changed	1	0	1
		Surgical and medical procedures	1	0	1
	Vascular disorders	Peripheral ischaemia	1	0	1
		Hypotension	1	0	1
		Flushing	1	0	1
Pallor		2	0	0	
Hypertension		1	0	0	
Vascular disorders		6	0	3	
Reaction			362	7	266