

**Medicines summary methylphenidate hcl (all to date)**

			Case Group	Death Outcomes	Sole
Case Count			179	3	143
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	0	1
		Aplastic anaemia	1	0	1
		Pancytopenia	1	0	1
		<b>Blood and lymphatic system disorders</b>	<b>4</b>	<b>0</b>	<b>3</b>
	Cardiac disorders	Arrhythmia	1	0	1
		Tachycardia	6	0	6
		Cardiac arrest	1	0	1
		Ventricular fibrillation	1	0	1
		Palpitations	5	0	3
		Myocardial infarction	1	0	0
		Cardiomyopathy	1	0	1
		<b>Cardiac disorders</b>	<b>16</b>	<b>0</b>	<b>13</b>
	Congenital, familial and genetic disorders	Tourette's disorder	2	0	2
		<b>Congenital, familial and genetic disorders</b>	<b>2</b>	<b>0</b>	<b>2</b>
	Endocrine disorders	Hypothyroidism	1	0	1
		<b>Endocrine disorders</b>	<b>1</b>	<b>0</b>	<b>1</b>
	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
		Eye movement disorder	1	0	1
		Oculogyric crisis	2	0	2
		Photophobia	3	0	1
		Optic atrophy	1	0	1
		Retinal pigmentation	1	0	0
		Accommodation disorder	1	0	1
		Vision blurred	4	0	3
		Visual impairment	2	0	2
		<b>Eye disorders</b>	<b>20</b>	<b>0</b>	<b>14</b>
		Gastrointestinal disorders	Tooth discolouration	1	0
	Gingival hyperplasia		2	0	1
	Pancreatitis		2	0	2
Gastrointestinal inflammation	1		0	1	
Diarrhoea	5		0	3	
Abdominal pain	5		0	4	
Abdominal pain upper	2		0	2	
Abdominal discomfort	1		0	1	
Nausea	9		1	8	
Vomiting	6		1	6	
Duodenal scarring	1		0	1	

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			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Chapped lips	1	0	1
		Lip swelling	2	0	1
		Mouth ulceration	1	0	0
		Dry mouth	1	0	1
		<b>Gastrointestinal disorders</b>	<b>40</b>	<b>2</b>	<b>33</b>
	General disorders and administration site conditions	Pyrexia	2	0	1
		Sudden death	2	2	1
		Fatigue	6	0	3
		Malaise	2	0	2
		Abasia	1	0	0
		Condition aggravated	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	3	0	1
		Pain	4	0	4
		Chest discomfort	2	0	2
		Feeling abnormal	3	0	3
		Drug interaction	3	0	0
		Drug effect decreased	2	0	1
		Drug ineffective	14	0	11
		Therapeutic response decreased	1	0	1
		Drug withdrawal syndrome	1	0	1
		Mass	1	0	1
		Product quality issue	1	0	1
		<b>General disorders and administration site conditions</b>	<b>54</b>	<b>2</b>	<b>37</b>
	Immune system disorders	Anaphylactic shock	1	0	1
		<b>Immune system disorders</b>	<b>1</b>	<b>0</b>	<b>1</b>
	Infections and infestations	Otitis media	1	0	0
		Infection	2	0	2
		Pharyngitis	2	0	0
		Rhinitis	1	0	0
		Cystitis	1	0	1
		Viral infection	1	0	0
		<b>Infections and infestations</b>	<b>8</b>	<b>0</b>	<b>3</b>
	Injury, poisoning and procedural complications	Fall	1	0	0
		Wrong drug administered	1	0	0
		Intentional overdose	1	0	1
		<b>Injury, poisoning and procedural complications</b>	<b>3</b>	<b>0</b>	<b>1</b>

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			Case Group	Death Outcomes	Sole
Reaction Count	Investigations	Electrocardiogram QT prolonged	1	0	1
		Electrocardiogram abnormal	2	0	1
		Heart rate increased	3	0	2
		Heart rate irregular	1	0	0
		Blood pressure increased	1	0	1
		Androgens increased	1	0	1
		Bleeding time prolonged	1	0	0
		Prothrombin level decreased	1	0	0
		Corneal reflex decreased	1	0	1
		Intraocular pressure increased	1	0	1
		Weight decreased	5	0	4
		Weight increased	2	0	2
			<b>Investigations</b>	<b>20</b>	<b>0</b>
Metabolism and nutrition disorders		Anorexia	8	0	7
		Decreased appetite	1	0	1
		Increased appetite	1	0	1
		Obesity	2	0	2
		Polydipsia	2	0	2
			<b>Metabolism and nutrition disorders</b>	<b>14</b>	<b>0</b>
Musculoskeletal and connective tissue disorders		Pain in jaw	1	0	1
		Myalgia	2	0	2
		Muscle spasms	1	0	1
		Muscle twitching	7	0	5
		Muscle rigidity	1	0	0
		Growth retardation	2	0	2
		Sensation of heaviness	1	0	1
		Back pain	1	0	1
			<b>Musculoskeletal and connective tissue disorders</b>	<b>16</b>	<b>0</b>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Pseudolymphoma	1	0	0
		Neoplasm malignant	1	0	1
			<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>2</b>	<b>0</b>
Nervous system disorders		Optic neuritis	1	0	1
		Headache	13	0	9
		Migraine	1	0	1
		Migraine with aura	1	0	1
		Dementia	1	0	1
		Amnesia	2	0	2
		Disturbance in attention	1	0	1
		Choreoathetosis	1	0	1
		Dyskinesia	8	0	6

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			Case Group	Death Outcomes	Sole		
Reaction Count	Nervous system disorders	Extrapyramidal disorder	2	0	1		
		Hyperkinesia	2	0	2		
		Psychomotor hyperactivity	1	0	1		
		Tardive dyskinesia	1	0	1		
		Dystonia	5	0	4		
		Tremor	6	0	5		
		Ataxia	1	0	0		
		Coma	1	0	0		
		Lethargy	2	0	1		
		Somnolence	7	0	4		
		Syncope	1	0	1		
		Dizziness	3	0	1		
		Crying	2	0	2		
		Formication	1	0	0		
		Hyperaesthesia	2	0	1		
		Paraesthesia	1	0	0		
		Dysgeusia	1	0	1		
		Dysarthria	1	0	0		
		Visual field defect	1	0	1		
		Hypertonia	2	0	1		
		Neuroleptic malignant syndrome	1	0	1		
		Convulsion	1	0	0		
		Poor quality sleep	1	0	0		
			<b>Nervous system disorders</b>	<b>75</b>	<b>0</b>	<b>51</b>	
		Reaction Count	Psychiatric disorders	Agitation	6	0	4
				Anxiety	7	0	5
				Nervousness	4	0	4
Fear	1			0	1		
Panic attack	1			0	1		
Neurosis	4			0	3		
Obsessive thoughts	2			0	2		
Obsessive-compulsive disorder	2			0	1		
Restlessness	1			0	0		
Head banging	1			0	1		
Tic	8			0	8		
Distractibility	1			0	0		
Logorrhoea	1			0	1		
Lack of spontaneous speech	1			0	1		
Confusional state	5			1	3		
Disorientation	1			0	1		
Depression	12			0	11		
Tearfulness	1	0	1				

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			Case Group	Death Outcomes	Sole		
Reaction Count	Psychiatric disorders	Hallucination	8	1	7		
		Hallucination, auditory	2	0	2		
		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	3	0	3		
		Emotional disorder	1	0	1		
		Emotional distress	1	0	1		
		Mood altered	1	0	1		
		Mood swings	1	0	1		
		Apathy	1	0	0		
		Aggression	8	0	8		
		Asocial behaviour	1	0	1		
		Disturbance in social behaviour	1	0	1		
		Paranoia	5	0	5		
		Social avoidant behaviour	1	0	1		
		Abnormal behaviour	3	0	3		
		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	5	0	5		
		Abnormal sleep-related event	1	0	0		
		Nightmare	1	0	1		
		Sleep disorder	1	0	1		
		Intentional self-injury	1	0	1		
		Self injurious behaviour	1	0	1		
		Suicidal ideation	4	0	3		
		Suicide attempt	4	0	4		
			<b>Psychiatric disorders</b>		<b>130</b>	<b>2</b>	<b>111</b>
			Renal and urinary disorders	Renal failure acute	1	1	1
	Pollakiuria	1		0	1		
	Haematuria	1		0	1		
	Polyuria	2		0	2		
	<b>Renal and urinary disorders</b>			<b>5</b>	<b>1</b>	<b>5</b>	
	Respiratory, thoracic and mediastinal disorders	Wheezing	2	0	2		
		Pulmonary embolism	1	0	1		
		Dyspnoea	5	0	2		

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			Case Group	Death Outcomes	Sole
Reaction Count	Respiratory, thoracic and mediastinal disorders	Cough	1	0	0
		Oropharyngeal pain	1	0	1
		Stridor	1	0	0
		Epistaxis	1	0	1
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>12</b>	<b>0</b>	<b>7</b>
	Skin and subcutaneous tissue disorders	Angioedema	3	0	2
		Urticaria	3	0	3
		Erythema multiforme	1	0	0
		Stevens-Johnson syndrome	1	0	0
		Skin lesion	1	0	1
		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	9	0	8
		Henoch-Schonlein purpura	1	0	1
		<b>Skin and subcutaneous tissue disorders</b>	<b>35</b>	<b>0</b>	<b>26</b>
	Social circumstances	Physical assault	1	0	1
		Sexual abuse	1	0	0
		<b>Social circumstances</b>	<b>2</b>	<b>0</b>	<b>1</b>
	Surgical and medical procedures	Therapy regimen changed	1	0	1
		<b>Surgical and medical procedures</b>	<b>1</b>	<b>0</b>	<b>1</b>
	Vascular disorders	Peripheral ischaemia	1	0	1
		Hypotension	1	0	1
Flushing		1	0	1	
Pallor		2	0	0	
Hypertension		1	0	0	
<b>Vascular disorders</b>		<b>6</b>	<b>0</b>	<b>3</b>	
<b>Reaction</b>			<b>467</b>	<b>7</b>	<b>354</b>