



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

Atomoxetine Hydrochloride		Layer 1 of 8	
		<b>ALL REPORT DATES</b>	
		Causality Unclear Exclud	
		Total	Sole Suspected
<b>- Cases Including Medicine</b>		50	40
<b>- Occurrences of Medicine</b>		50	40
<b>- Reactions Related to Medicine</b>		159	140
Blood and lymphatic system disorders	Coagulopathy	1	0
Cardiac disorders	Tachycardia	2	1
	Supraventricular tachycardia	1	1
	Palpitations	1	0
Eye disorders	Eyelid ptosis	1	1
	Strabismus	1	1
	Visual disturbance	1	1
Gastrointestinal disorders	Pancreatitis	1	1
	Gastrointestinal disorder	2	2
	Diarrhoea	1	1
	Dyspepsia	1	1
	Abdominal pain	1	1
	Abdominal pain upper	2	2
	Faecal incontinence	1	1
	Nausea	4	3
	Vomiting	5	5
General disorders and administration site conditions	Feeling cold	1	1
	Feeling hot	1	0
	Condition aggravated	1	0
	Irritability	1	1
	Chest pain	2	2
	Pain	1	1
	Drug interaction	1	0
	Drug ineffective	3	2
Hepatobiliary disorders	Hepatitis	1	1
Infections and infestations	Orchitis	1	1
Injury, poisoning and procedural complications	Fall	1	1
Investigations	Heart rate increased	1	1



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

Atomoxetine Hydrochloride		Layer 1 of 8	
Investigations	Blood pressure increased	1	1
	Visual acuity tests abnormal	1	1
	Weight decreased	1	1
Metabolism and nutrition disorders	Anorexia	2	1
Musculoskeletal and connective tissue disorders	Arthralgia	1	1
	Joint swelling	1	1
	Muscle rigidity	1	1
	Growth retardation	1	0
Nervous system disorders	Facial spasm	1	1
	Headache	6	5
	Intracranial pressure increased	1	1
	Disturbance in attention	1	1
	Psychomotor hyperactivity	1	1
	Syncope	2	2
	Motor dysfunction	1	1
	Dizziness	4	4
	Paraesthesia	1	1
	Hypoaesthesia	1	1
	Convulsion	3	0
Psychiatric disorders	Obsessive-compulsive disorder	1	1
	Agitation	4	4
	Anxiety	4	4
	Nervousness	1	1
	Panic attack	1	1
	Restlessness	1	1
	Tic	1	1
	Paramnesia	1	1
	Depression	3	2
	Major depression	1	1
	Depressed mood	3	3
	Tearfulness	1	1
	Hallucination, auditory	3	2
	Thinking abnormal	1	1
	Affect lability	2	2
Anger	2	2	



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

Atomoxetine Hydrochloride		Layer 1 of 8	
Psychiatric disorders	Emotional disorder	1	1
	Mood altered	1	1
	Mood swings	2	2
	Aggression	7	7
	Attention-seeking behaviour	1	1
	Homicidal ideation	1	0
	Hostility	1	1
	Social avoidant behaviour	1	1
	Abnormal behaviour	4	4
	Regressive behaviour	1	1
	Mental disorder	1	1
	Psychotic disorder	3	3
	Insomnia	1	1
	Sleep disorder	1	1
	Intentional self-injury	1	1
	Self injurious behaviour	3	3
	Self-injurious ideation	1	1
	Suicidal ideation	14	12
	Suicide attempt	2	2
Renal and urinary disorders	Urinary incontinence	1	1
Reproductive system and breast disorders	Balanitis	1	1
Respiratory, thoracic and mediastinal disorders	Cough	1	1
	Throat tightness	1	1
Skin and subcutaneous tissue disorders	Periorbital oedema	1	1
	Rash	1	1
Social circumstances	Educational problem	1	1
Surgical and medical procedures	Therapy regimen changed	1	1
Vascular disorders	Pallor	1	1
	Hypertension	1	1



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

DEXAMPHETAMINE SULPHATE		Layer 2 of 8	
		<b>ALL REPORT DATES</b>	
		Causality Unclear Exclud	
		Total	Sole Suspected
<b>- Cases Including Medicine</b>		65	39
<b>- Occurrences of Medicine</b>		66	39
<b>- Reactions Related to Medicine</b>		157	93
Blood and lymphatic system disorders	Neutropenia	1	0
Cardiac disorders	Tachycardia	5	1
	Palpitations	2	1
	Cardiomyopathy	1	1
Congenital, familial and genetic disorders	Multiple congenital abnormalitie	1	1
Ear and labyrinth disorders	Hearing impaired	1	1
	Tinnitus	1	1
Eye disorders	Mydriasis	1	0
	Photophobia	1	1
	Retinal pigmentation	1	0
	Vision blurred	1	1
Gastrointestinal disorders	Abdominal pain	2	2
	Vomiting	1	0
	Cheilitis	1	1
	Stomatitis	1	1
	Dry mouth	2	2
General disorders and administration site conditions	Chills	3	1
	Asthenia	2	0
	Fatigue	1	1
	Abasia	1	1
	Irritability	1	1
	Face oedema	1	1
	Drug effect decreased	1	1
	Drug ineffective	1	0
	Therapeutic response decrease	1	0
Investigations	Electroencephalogram abnorm	1	0
	Weight decreased	1	1
Metabolism and nutrition disorders	Anorexia	1	1

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

DEXAMPHETAMINE SULPHATE		Layer 2 of 8	
Metabolism and nutrition disorders	Hyponatraemia	1	0
	Hypoglycaemia	1	0
Musculoskeletal and connective tissue disorders	Myalgia	1	0
	Muscle spasms	1	0
	Muscle twitching	3	3
Nervous system disorders	Subarachnoid haemorrhage	1	1
	Headache	1	1
	Disturbance in attention	2	2
	Judgement impaired	1	1
	Dyskinesia	2	1
	Hyperkinesia	4	0
	Dystonia	2	0
	Tremor	4	3
	Hyperreflexia	1	0
	Hyporeflexia	1	0
	Dizziness	1	1
	Burning sensation mucosal	1	1
	Paraesthesia	1	1
	Neuralgia	1	0
	Dysarthria	1	1
	Speech disorder	1	0
	Hypertonia	4	0
	Hypotonia	1	0
	Serotonin syndrome	1	0
	Muscle contractions involuntary	1	0
Convulsion	2	0	
Pregnancy, puerperium and perinatal conditions	Neonatal disorder	1	1
Psychiatric disorders	Neurosis	1	0
	Obsessive-compulsive disorder	2	0
	Agitation	7	2
	Anxiety	3	0
	Nervousness	3	1
	Restlessness	1	1
	Confusional state	2	1
	Disorientation	1	1

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

DEXAMPHETAMINE SULPHATE		Layer 2 of 8	
Psychiatric disorders	Depression	1	1
	Depressed mood	1	1
	Delusion	3	3
	Hallucination	2	0
	Hallucination, auditory	2	2
	Hallucination, visual	1	1
	Thinking abnormal	1	1
	Anger	1	1
	Crying	1	1
	Mood swings	2	2
	Apathy	1	1
	Aggression	5	5
	Homicidal ideation	1	1
	Paranoia	1	1
	Abnormal behaviour	2	2
	Neglect of personal appearance	1	1
	Psychotic disorder	2	1
	Insomnia	4	4
Suicidal ideation	2	2	
Renal and urinary disorders	Renal pain	1	1
Reproductive system and breast disorders	Testicular disorder	1	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	1
	Dyspnoea	1	1
	Hyperventilation	1	0
Skin and subcutaneous tissue disorders	Periorbital oedema	1	1
	Urticaria	1	1
	Erythema	1	1
	Rash erythematous	2	1
	Pruritus	3	3
	Rash	2	2
	Skin ulcer	1	1
	Alopecia	1	0
	Hyperhidrosis	1	0
	Nail discolouration	1	1
	Purpura	1	1



# THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

DEXAMPHETAMINE SULPHATE		Layer 2 of 8	
Surgical and medical procedures	Therapy regimen changed	1	0
Vascular disorders	Peripheral ischaemia	1	1
	Orthostatic hypotension	1	1

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

METHYLPHENIDATE HYDROCHLORIDE		Layer 3 of 8		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		158	3	124
<b>- Occurrences of Medicine</b>		160	3	124
<b>- Reactions Related to Medicine</b>		418	7	307
Blood and lymphatic system disorders	Anaemia	2	0	1
	Aplastic anaemia	1	0	1
	Pancytopenia	1	0	1
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
Congenital, familial and genetic disorders	Tourette's disorder	1	0	1
Endocrine disorders	Hypothyroidism	1	0	1
Eye disorders	Eye oedema	1	0	1
	Eye pain	1	0	0
	Conjunctivitis	1	0	0
	Oculogyric crisis	2	0	2
	Photophobia	2	0	0
	Optic atrophy	1	0	1
	Retinal pigmentation	1	0	0
	Vision blurred	4	0	3
	Visual disturbance	2	0	2
Gastrointestinal disorders	Tooth discolouration	1	0	1
	Gingival hyperplasia	2	0	1
	Pancreatitis	2	0	2
	Gastrointestinal inflammation	1	0	1
	Diarrhoea	5	0	3
	Abdominal pain	4	0	3
	Abdominal pain upper	2	0	2



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

METHYLPHENIDATE HYDROCHLORIDE		Layer 3 of 8		
Gastrointestinal disorders	Abdominal discomfort	1	0	1
	Nausea	9	1	8
	Vomiting	6	1	6
	Duodenal scarring	1	0	1
	Lip swelling	2	0	0
	Mouth ulceration	1	0	0
	Dry mouth	1	0	1
General disorders and administration site conditions	Pyrexia	2	0	1
	Sudden death	2	2	1
	Fatigue	5	0	2
	Malaise	1	0	1
	Abasia	1	0	0
	Chest discomfort	2	0	2
	Condition aggravated	1	0	1
	Feeling abnormal	3	0	3
	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	3	0	3
	Drug interaction	3	0	0
	Drug effect decreased	2	0	1
	Drug ineffective	13	0	10
	Drug withdrawal syndrome	1	0	1
	Mass	1	0	1
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
Injury, poisoning and procedural complications	Fall	1	0	0
	Wrong drug administered	1	0	0
Investigations	Electrocardiogram abnormal	3	0	1

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

METHYLPHENIDATE HYDROCHLORIDE		Layer 3 of 8		
Investigations	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	4	0	3
	Weight increased	2	0	2
	Metabolism and nutrition disorders	Anorexia	8	0
Decreased appetite		1	0	1
Increased appetite		1	0	1
Obesity		2	0	2
Polydipsia		2	0	2
Musculoskeletal and connective tissue disorders	Pain in jaw	1	0	1
	Myalgia	2	0	2
	Muscle twitching	7	0	5
	Muscle rigidity	1	0	0
	Growth retardation	1	0	1
	Sensation of heaviness	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	1	0	0
	Neoplasm malignant	1	0	1
Nervous system disorders	Optic neuritis	1	0	1
	Headache	12	0	8
	Migraine	1	0	1
	Dementia	1	0	1
	Amnesia	2	0	2
	Choreoathetosis	1	0	1
	Dyskinesia	8	0	6
	Extrapyramidal disorder	2	0	1
	Hyperkinesia	2	0	2
	Psychomotor hyperactivity	1	0	1
	Tardive dyskinesia	1	0	1
	Dystonia	5	0	4

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

METHYLPHENIDATE HYDROCHLORIDE		Layer 3 of 8			
Nervous system disorders	Tremor	5	0	4	
	Ataxia	1	0	0	
	Coma	1	0	0	
	Lethargy	2	0	1	
	Somnolence	7	0	4	
	Dizziness	3	0	1	
	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 syndrom	1	0	1	
	Poor quality sleep	1	0	0	
	Psychiatric disorders	Neurosis	4	0	3
		Obsessive-compulsive disorder	1	0	0
Agitation		6	0	4	
Anxiety		6	0	4	
Nervousness		4	0	4	
Obsessive thoughts		1	0	1	
Fear		1	0	1	
Panic attack		1	0	1	
Restlessness		1	0	0	
Head banging		1	0	1	
Tic		6	0	6	
Distractibility		1	0	0	
Logorrhoea		1	0	1	
Lack of spontaneous speech		1	0	1	
Confusional state		4	1	2	
Disorientation		1	0	1	
Depression		11	0	10	
Tearfulness		1	0	1	
Hallucination		7	1	6	
Hallucination, auditory		2	0	2	



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

METHYLPHENIDATE HYDROCHLORIDE		Layer 3 of 8		
Psychiatric disorders	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
	Crying	2	0	2
	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	7	0	7
	Asocial behaviour	1	0	1
	Disturbance in social behaviour	1	0	1
	Paranoia	4	0	4
	Social avoidant behaviour	1	0	1
	Abnormal behaviour	2	0	2
	Psychiatric symptom	1	0	1
	Drug dependence	1	0	1
	Withdrawal syndrome	2	0	1
	Psychotic disorder	2	0	2
	Insomnia	4	0	4
	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	2	0	1
	Suicide attempt	2	0	2
Renal and urinary disorders	Renal failure acute	1	1	1
	Pollakiuria	1	0	1
	Polyuria	2	0	2
Respiratory, thoracic and mediastinal disorders	Wheezing	1	0	1
	Pulmonary embolism	1	0	1

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

METHYLPHENIDATE HYDROCHLORIDE		Layer 3 of 8		
Respiratory, thoracic and mediastinal disorders	Dyspnoea	4	0	1
	Cough	1	0	0
	Pharyngolaryngeal pain	1	0	1
	Stridor	1	0	0
	Epistaxis	1	0	1
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	10	0	9
	Henoch-Schonlein purpura	1	0	1
Social circumstances	Physical assault	1	0	1
	Pharmaceutical product complaint	1	0	1
Surgical and medical procedures	Therapy regimen changed	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



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

ATTENTA

Layer 4 of 8

		ALL REPORT DATES	
		Causality Unclear Exclud	
		Total	Sole Suspected
<b>- Cases Including Medicine</b>		4	4
<b>- Occurrences of Medicine</b>		4	4
<b>- Reactions Related to Medicine</b>		18	18
Cardiac disorders	Tachycardia	1	1
Gastrointestinal disorders	Gastrointestinal inflammation	1	1
	Abdominal pain	1	1
	Vomiting	1	1
General disorders and administration site conditions	Chest discomfort	1	1
	Pain	1	1
	Drug ineffective	1	1
Investigations	Blood pressure increased	1	1
Metabolism and nutrition disorders	Polydipsia	1	1
Nervous system disorders	Migraine	1	1
Psychiatric disorders	Agitation	2	2
	Depression	1	1
	Aggression	1	1
	Abnormal behaviour	1	1
Renal and urinary disorders	Polyuria	1	1
Skin and subcutaneous tissue disorders	Angioedema	1	1
	Hyperhidrosis	1	1



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

Concerta		Layer 5 of 8	
		ALL REPORT DATES	
		Causality Unclear Exclud	
		Total	Sole Suspected
<b>- Cases Including Medicine</b>		12	12
<b>- Occurrences of Medicine</b>		12	12
<b>- Reactions Related to Medicine</b>		34	34
Congenital, familial and genetic disorders	Tourette's disorder	1	1
General disorders and administration site conditions	Condition aggravated	1	1
	Drug ineffective	1	1
Investigations	Weight increased	1	1
Metabolism and nutrition disorders	Anorexia	2	2
Musculoskeletal and connective tissue disorders	Muscle twitching	1	1
Nervous system disorders	Headache	1	1
	Dyskinesia	2	2
	Dystonia	1	1
	Hyperaesthesia	1	1
Psychiatric disorders	Obsessive thoughts	1	1
	Fear	1	1
	Head banging	1	1
	Tic	3	3
	Logorrhoea	1	1
	Hallucination	2	2
	Anger	1	1
	Emotional disorder	1	1
	Mood swings	1	1
	Aggression	2	2
	Disturbance in social behaviour	1	1
	Paranoia	1	1
	Insomnia	1	1
	Self injurious behaviour	1	1
Skin and subcutaneous tissue disorders	Skin lesion	1	1
	Hyperhidrosis	2	2
	Henoch-Schonlein purpura	1	1

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

METHYLPHENIDATE HYDROCHLORIDE		Layer 6 of 8	
		ALL REPORT DATES	
		Causality	Unclear Exclud
		Total	Sole Suspected
<b>- Cases Including Medicine</b>		9	5
<b>- Occurrences of Medicine</b>		9	5
<b>- Reactions Related to Medicine</b>		29	12
Eye disorders	Photophobia	1	0
General disorders and administration site conditions	Abasia	1	0
	Drug interaction	1	0
	Drug ineffective	1	0
Injury, poisoning and procedural complications	Wrong drug administered	1	0
Investigations	Bleeding time prolonged	1	0
	Corneal reflex decreased	1	1
Musculoskeletal and connective tissue disorders	Muscle twitching	1	0
	Muscle rigidity	1	0
Nervous system disorders	Headache	1	0
	Dyskinesia	1	0
	Extrapyramidal disorder	1	0
	Dystonia	1	0
	Tremor	1	1
	Hyperaesthesia	1	0
	Paraesthesia	1	0
	Dysarthria	1	0
	Hypertonia	1	0
Psychiatric disorders	Anxiety	1	1
	Tic	1	1
	Depression	1	1
	Hallucination, auditory	2	2
	Anger	1	1
	Emotional distress	1	1
	Paranoia	2	2
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1	1
	Dyspnoea	1	0



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

RITALIN		Layer 7 of 8		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		105	3	76
<b>- Occurrences of Medicine</b>		106	3	76
<b>- Reactions Related to Medicine</b>		253	7	167
Blood and lymphatic system disorders	Anaemia	1	0	1
	Aplastic anaemia	1	0	1
	Pancytopenia	1	0	1
Cardiac disorders	Tachycardia	3	0	3
	Cardiac arrest	1	0	1
	Ventricular fibrillation	1	0	1
	Palpitations	3	0	2
	Myocardial infarction	1	0	0
	Cardiomyopathy	1	0	1
Eye disorders	Eye oedema	1	0	1
	Eye pain	1	0	0
	Conjunctivitis	1	0	0
	Oculogyric crisis	2	0	2
	Photophobia	1	0	0
	Optic atrophy	1	0	1
	Retinal pigmentation	1	0	0
	Vision blurred	3	0	2
Gastrointestinal disorders	Tooth discolouration	1	0	1
	Gingival hyperplasia	2	0	1
	Pancreatitis	2	0	2
	Diarrhoea	4	0	2
	Abdominal pain	3	0	2
	Abdominal pain upper	1	0	1
	Abdominal discomfort	1	0	1
	Nausea	7	1	6
	Vomiting	3	1	3
	Duodenal scarring	1	0	1
	Lip swelling	2	0	0



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

RITALIN		Layer 7 of 8		
Gastrointestinal disorders	Mouth ulceration	1	0	0
General disorders and administration site conditions	Pyrexia	2	0	1
	Sudden death	2	2	1
	Fatigue	3	0	1
	Chest discomfort	1	0	1
	Feeling abnormal	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	1	0	1
	Drug interaction	2	0	0
	Drug effect decreased	2	0	1
	Drug ineffective	7	0	5
	Mass	1	0	1
	Infections and infestations	Otitis media	1	0
Infection		2	0	2
Pharyngitis		2	0	0
Rhinitis		1	0	0
Viral infection		1	0	0
Injury, poisoning and procedural complications	Fall	1	0	0
Investigations	Electrocardiogram abnormal	2	0	0
	Heart rate increased	1	0	0
	Androgens increased	1	0	1
	Prothrombin level decreased	1	0	0
	Weight decreased	4	0	3
Metabolism and nutrition disorders	Anorexia	5	0	4
	Decreased appetite	1	0	1
	Polydipsia	1	0	1
Musculoskeletal and connective tissue disorders	Pain in jaw	1	0	1
	Myalgia	2	0	2
	Muscle twitching	4	0	3
	Growth retardation	1	0	1

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

RITALIN		Layer 7 of 8		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	1	0	0
	Neoplasm malignant	1	0	1
Nervous system disorders	Optic neuritis	1	0	1
	Headache	6	0	3
	Dementia	1	0	1
	Amnesia	2	0	2
	Dyskinesia	5	0	4
	Extrapyramidal disorder	1	0	1
	Hyperkinesia	2	0	2
	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	5	0	3
	Dizziness	2	0	0
	Formication	1	0	0
	Dysgeusia	1	0	1
	Visual field defect	1	0	1
	Hypertonia	1	0	1
	Neuroleptic malignant syndrom	1	0	1
Poor quality sleep	1	0	0	
Psychiatric disorders	Neurosis	4	0	3
	Obsessive-compulsive disorder	1	0	0
	Agitation	3	0	1
	Anxiety	2	0	1
	Nervousness	3	0	3
	Restlessness	1	0	0
	Tic	1	0	1
	Distractibility	1	0	0
	Confusional state	3	1	1
	Depression	6	0	5
	Tearfulness	1	0	1
	Hallucination	4	1	3

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

RITALIN		Layer 7 of 8		
Psychiatric disorders	Thinking abnormal	1	0	1
	Mania	1	0	1
	Inappropriate affect	1	0	0
	Crying	1	0	1
	Apathy	1	0	0
	Aggression	4	0	4
	Asocial behaviour	1	0	1
	Paranoia	1	0	1
	Social avoidant behaviour	1	0	1
	Drug dependence	1	0	1
	Withdrawal syndrome	1	0	0
	Psychotic disorder	1	0	1
	Insomnia	3	0	3
	Abnormal sleep-related event	1	0	0
	Nightmare	1	0	1
	Sleep disorder	1	0	1
	Suicidal ideation	2	0	1
	Suicide attempt	2	0	2
Renal and urinary disorders	Renal failure acute	1	1	1
	Pollakiuria	1	0	1
	Polyuria	1	0	1
Respiratory, thoracic and mediastinal disorders	Dyspnoea	3	0	1
	Cough	1	0	0
	Pharyngolaryngeal pain	1	0	1
	Stridor	1	0	0
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
	Rash erythematous	1	0	0
	Pruritus	2	0	2
	Rash	4	0	3
	Rash maculo-papular	1	0	0
	Alopecia	4	0	4



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

RITALIN		Layer 7 of 8		
Skin and subcutaneous tissue disorders	Cold sweat	1	0	1
	Hyperhidrosis	5	0	4
Social circumstances	Physical assault	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



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

Ritalin LA		Layer 8 of 8	
		<b>ALL REPORT DATES</b>	
		Causality Unclear Exclud	
		Total	Sole Suspected
<b>- Cases Including Medicine</b>		29	27
<b>- Occurrences of Medicine</b>		29	27
<b>- Reactions Related to Medicine</b>		86	76
Blood and lymphatic system disorders	Anaemia	1	0
Cardiac disorders	Arrhythmia	1	1
	Tachycardia	2	2
	Palpitations	2	1
Endocrine disorders	Hypothyroidism	1	1
Eye disorders	Vision blurred	1	1
	Visual disturbance	2	2
Gastrointestinal disorders	Diarrhoea	1	1
	Abdominal pain upper	1	1
	Nausea	2	2
	Vomiting	2	2
	Dry mouth	1	1
General disorders and administration site conditions	Fatigue	2	1
	Malaise	1	1
	Feeling abnormal	1	1
	Pain	1	1
	Drug ineffective	3	3
	Drug withdrawal syndrome	1	1
Investigations	Electrocardiogram abnormal	1	1
	Heart rate increased	2	2
	Heart rate irregular	1	0
	Intraocular pressure increased	1	1
	Weight increased	1	1
Metabolism and nutrition disorders	Anorexia	1	1
	Increased appetite	1	1
	Obesity	2	2
Musculoskeletal and connective tissue disorders	Muscle twitching	1	1
	Sensation of heaviness	1	1



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

Ritalin LA		Layer 8 of 8	
Nervous system disorders	Headache	4	4
	Choreoathetosis	1	1
	Psychomotor hyperactivity	1	1
	Tremor	1	1
	Lethargy	1	0
	Somnolence	2	1
	Dizziness	1	1
Psychiatric disorders	Agitation	1	1
	Anxiety	3	2
	Nervousness	1	1
	Panic attack	1	1
	Tic	1	1
	Lack of spontaneous speech	1	1
	Confusional state	1	1
	Disorientation	1	1
	Depression	3	3
	Hallucination	1	1
	Hallucination, visual	1	1
	Affect lability	2	2
	Anger	1	1
	Crying	1	1
	Mood altered	1	1
	Abnormal behaviour	1	1
	Psychiatric symptom	1	1
	Withdrawal syndrome	1	1
Psychotic disorder	1	1	
Intentional self-injury	1	1	
Respiratory, thoracic and mediastinal disorders	Wheezing	1	1
	Epistaxis	1	1
Skin and subcutaneous tissue disorders	Urticaria	2	2
	Pruritus	1	0
	Rash	1	0
	Rash maculo-papular	1	0
	Cold sweat	1	1
	Hyperhidrosis	2	2



# THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

Ritalin LA		Layer 8 of 8	
Social circumstances	Pharmaceutical product compl	1	1
Surgical and medical procedures	Therapy regimen changed	1	1