

risperidone to end January 2009

				Case Group	Death Outcomes	Sole
Case Count				985	31	658
Medicine	Reaction Count	Blood and lymphatic system disorders	Iron deficiency anaemia	1	0	1
			Anaemia	7	0	3
			Pancytopenia	6	0	3
			Thrombocythaemia	1	0	0
			Thrombocytopenia	7	2	3
			Lymphadenopathy	2	0	0
			Eosinophilia	3	0	1
			Leukocytosis	8	0	5
			Leukopenia	6	1	2
			Lymphopenia	1	0	0
			Agranulocytosis	6	0	2
			Febrile neutropenia	1	0	1
			Neutropenia	20	0	14
			Blood and lymphatic system disorders	69	3	35
		Cardiac disorders	Atrioventricular block	3	0	2
			Arrhythmia	4	0	3
			Bradycardia	6	0	2
			Tachycardia	15	0	10
			Atrial fibrillation	1	1	0
			Supraventricular tachycardia	4	0	2
			Cardiac arrest	5	3	2
			Ventricular fibrillation	1	0	0
			Palpitations	2	0	2
			Angina pectoris	1	0	1
			Myocardial infarction	6	2	4
			Cardiac failure	1	0	1
			Cardiac failure congestive	1	1	1
			Left ventricular failure	1	1	0
			Cardiomyopathy	3	0	1
			Cardiomegaly	1	1	0
			Myocarditis	3	0	0
			Pericarditis	2	0	2
			Cardiac disorders	60	9	33
			Congenital, familial and genetic disorders	Deafness congenital	1	0
		Cleft palate		2	0	2
		Cerebral palsy		1	0	0
		Tourette's disorder		1	0	1
		Congenital, familial and genetic disorders		5	0	3
		Ear and labyrinth disorders	Hyperacusis	1	0	1
			Ear and labyrinth disorders	1	0	1
		Endocrine disorders	Hyperprolactinaemia	50	0	41

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Endocrine disorders	Diabetes insipidus	1	0	0
			Inappropriate antidiuretic hormone secretion	2	0	1
			Goitre	1	0	0
			Hyperthyroidism	1	0	1
			Hypothyroidism	2	0	0
			Endocrine disorders	57	0	43
		Eye disorders	Lacrimation increased	1	0	1
			Eye oedema	1	0	1
			Eye pain	1	0	1
			Retinal disorder	1	0	0
			Glaucoma	1	0	1
			Conjunctivitis	1	0	0
			Eyelid oedema	1	0	1
			Ocular hyperaemia	1	0	1
			Blepharospasm	5	0	5
			Eyelid ptosis	1	0	1
			Oculogyric crisis	8	0	4
			Eye rolling	1	0	0
			Papilloedema	1	0	0
			Macular degeneration	1	0	0
			Retinal haemorrhage	1	0	0
			Retinopathy	1	0	1
			Visual acuity reduced	1	0	1
			Myopia	1	0	1
			Diplopia	1	0	0
			Vision blurred	10	0	8
			Visual impairment	4	0	3
			Eye disorders	44	0	30
			Gastrointestinal disorders	Gingivitis	1	0
		Pancreatitis		2	0	1
		Gastrointestinal disorder		2	0	2
		Haematemesis		1	0	0
		Haematochezia		1	0	1
		Diarrhoea		2	0	2
		Constipation		9	0	6
		Abdominal distension		3	0	3
Flatulence	1	0		1		
Abdominal pain	6	0		1		
Abdominal pain upper	2	0		2		
Breath odour	1	0		1		
Dysphagia	18	1		12		
Faecal incontinence	3	0		2		

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Gastrointestinal disorders	Nausea	12	0	8
			Vomiting	14	0	8
			Intestinal obstruction	2	0	0
			Duodenal ulcer haemorrhage	1	0	0
			Thrombosis mesenteric vessel	1	0	1
			Lip oedema	2	0	2
			Lip swelling	1	0	1
			Oral mucosal eruption	1	0	1
			Retroperitoneal fibrosis	1	0	1
			Dry mouth	5	0	2
			Saliva altered	1	0	0
			Salivary hypersecretion	14	0	7
			Salivary gland enlargement	1	0	0
			Swollen tongue	5	0	5
			Tongue oedema	6	0	5
			Tongue spasm	2	0	2
			Gastrointestinal disorders	121	1	78
			General disorders and administration site conditions	Injection site mass	1	0
		Injection site pain		2	0	2
		Injection site reaction		2	0	2
		Hyperthermia malignant		2	0	1
		Hypothermia		3	0	2
		Pyrexia		38	1	11
		Death		6	5	6
		Sudden death		3	3	3
		Asthenia		6	0	6
		Fatigue		15	0	11
		Malaise		7	0	3
		Abasia		2	0	2
		Gait disturbance		13	0	12
		Condition aggravated		1	0	1
		Exercise tolerance decreased		1	0	1
		Influenza like illness		6	0	2
		Irritability		1	0	1
		Mucosal inflammation		1	0	0
		Face oedema		12	0	6
		Gravitational oedema		3	0	0
		Oedema		4	0	1
		Oedema peripheral		9	0	9
		Chest pain		5	0	3
		Pain		1	0	1
		Chest discomfort	2	0	2	

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	General disorders and administration site conditions	Chills	3	0	2
			Feeling abnormal	5	0	4
			Feeling jittery	2	0	0
			Thirst	3	0	2
			Drug interaction	3	0	0
			Food interaction	1	0	1
			Drug ineffective	13	0	11
			Therapeutic response decreased	4	0	3
			Drug withdrawal syndrome	3	0	3
			Drug withdrawal syndrome neonatal	4	0	1
			General disorders and administration site conditions	187	9	116
		Hepatobiliary disorders	Bile duct obstruction	1	0	0
			Gallbladder disorder	1	0	1
			Hepatitis cholestatic	1	0	1
			Jaundice	2	0	1
			Hepatic function abnormal	26	1	12
			Hepatomegaly	1	0	0
			Hepatic steatosis	1	1	0
			Hepatitis	5	0	0
			Hepatobiliary disorders	38	2	15
		Immune system disorders	Hypersensitivity	3	0	3
			Anaphylactoid reaction	1	0	1
			Immune system disorders	4	0	4
		Infections and infestations	Cellulitis	1	0	1
			Appendicitis	1	0	1
			Mastitis	1	0	1
			Hepatic infection	1	0	1
			Abscess	2	0	0
			Infection	3	0	3
			Lower respiratory tract infection	1	0	1
			Pneumonia	3	2	0
			Sepsis	3	1	0
			Pharyngitis	3	0	2
			Rhinitis	2	0	1
			Kidney infection	1	0	1
			Herpes zoster	1	0	1
			Infections and infestations	23	3	13
		Injury, poisoning and procedural complications	Drug toxicity	1	1	0
			Therapeutic agent toxicity	1	0	0
			Drug exposure during pregnancy	7	0	6
			Subdural haematoma	1	0	1
			Muscle injury	1	0	1

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Injury, poisoning and procedural complications	Tendon injury	1	0	1
			Fall	11	1	7
			Drug administration error	1	0	1
			Incorrect dose administered	1	1	0
			Incorrect route of drug administration	1	0	1
			Medication error	3	0	2
			Intentional overdose	1	0	0
			Overdose	6	1	5
			Injury, poisoning and procedural complications	36	4	25
		Investigations	Ejection fraction decreased	1	0	0
			Electrocardiogram QT prolonged	8	0	3
			Electrocardiogram T wave inversion	2	0	2
			Electrocardiogram abnormal	2	0	1
			Heart rate abnormal	1	0	1
			Heart rate increased	1	0	1
			Heart rate irregular	1	0	1
			Blood pressure decreased	1	0	1
			Blood pressure increased	1	0	0
			Blood prolactin increased	20	0	18
			Blood prolactin	1	0	1
			Blood testosterone decreased	1	0	1
			Blood testosterone increased	1	0	0
			Blood creatine phosphokinase increased	44	2	22
			Troponin increased	1	0	0
			Blood lactate dehydrogenase increased	1	0	1
			Prothrombin level increased	1	0	0
			Red blood cell sedimentation rate increased	2	0	0
			Neutrophil count decreased	1	0	1
			Alanine aminotransferase increased	2	0	0
			Aspartate aminotransferase increased	1	0	0
			Hepatic enzyme increased	3	0	1
			Liver function test abnormal	6	0	3
			Antiphospholipid antibodies positive	1	0	1
Blood triglycerides increased	1	0	1			
Oxygen saturation decreased	1	0	0			
Blood glucose fluctuation	1	0	1			
Blood glucose increased	2	0	2			
Electroencephalogram abnormal	1	0	1			
Body temperature fluctuation	1	0	1			
Weight decreased	5	0	1			
Weight increased	50	0	39			

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole	
			Sperm count abnormal	1	0	1
			Drug level above therapeutic	1	0	0
			Drug level increased	2	1	0
			Investigations	170	3	106
		Metabolism and nutrition disorders	Metabolic acidosis	1	0	0
			Anorexia	6	0	4
			Hypophagia	1	0	0
			Increased appetite	7	0	6
			Obesity	1	0	1
			Hypercalcaemia	1	1	0
			Hypomagnesaemia	1	1	0
			Diabetic ketoacidosis	1	0	0
			Hypochloraemia	1	1	0
			Polydipsia	4	0	2
			Hyperkalaemia	1	0	1
			Hypokalaemia	1	0	0
			Hypernatraemia	1	0	0
			Hyponatraemia	12	1	5
			Dehydration	3	1	2
			Diabetes mellitus	9	0	6
			Gestational diabetes	1	0	1
			Type 2 diabetes mellitus	2	0	1
			Glucose tolerance impaired	1	0	1
			Hyperglycaemia	5	0	0
			Hypoglycaemia	2	0	0
			Hypertriglyceridaemia	1	0	1
			Hyperproteinaemia	1	0	1
			Hypoproteinaemia	2	0	1
			Gout	1	0	0
			Vitamin B12 deficiency	1	0	1
			Metabolism and nutrition disorders	68	5	34
		Musculoskeletal and connective tissue disorders	Jaw disorder	1	0	1
			Systemic lupus erythematosus	1	0	1
			Synostosis	1	0	1
			Arthritis	1	0	0
			Arthralgia	1	0	0
			Joint stiffness	4	0	2
			Joint swelling	1	0	1
			Rheumatoid arthritis	1	0	1
			Myositis	1	0	1
			Myalgia	8	0	3
			Muscle disorder	1	0	1

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Musculoskeletal and connective tissue disorders	Muscle spasms	10	0	8
			Muscle twitching	5	0	3
			Muscle rigidity	14	0	9
			Nuchal rigidity	1	0	1
			Torticollis	3	0	2
			Trismus	3	0	2
			Muscular weakness	3	0	3
			Myopathy	2	0	0
			Rhabdomyolysis	4	0	3
			Mastication disorder	1	0	0
			Mobility decreased	6	0	3
			Muscle contracture	2	0	1
			Musculoskeletal stiffness	21	0	11
			Posture abnormal	1	0	1
			Back pain	5	0	4
			Flank pain	1	0	0
			Pain in extremity	5	0	4
			Musculoskeletal and connective tissue disorders	108	0	67
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	1	0
		Breast cancer female		6	0	6
		Breast cancer male		1	0	1
		Pituitary tumour benign		2	0	2
		Pituitary tumour		1	0	0
		Lip neoplasm		1	0	0
		Hairy cell leukaemia		1	0	0
		Metastases to lung		1	0	1
		Squamous cell carcinoma		1	0	0
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)		15	0	11
		Nervous system disorders		Cerebrovascular accident	14	3
			Cerebrovascular disorder	2	0	1
			Cranial nerve disorder	1	0	1
			Facial palsy	1	0	1
			Tongue paralysis	2	0	2
			Encephalopathy	1	0	0
			Toxic encephalopathy	1	0	0
			Headache	18	0	11
			Migraine	2	0	2
			Migraine with aura	1	0	1
			Intracranial pressure increased	2	0	1
			Dementia	3	0	2
			Amnesia	7	0	7

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Nervous system disorders	Disturbance in attention	1	0	0
			Choreoathetosis	1	0	1
			Akathisia	25	0	16
			Bradykinesia	1	0	0
			Dyskinesia	17	1	12
			Extrapyramidal disorder	47	0	34
			Hyperkinesia	13	0	9
			Hypokinesia	7	0	6
			Movement disorder	1	0	0
			Tardive dyskinesia	38	0	30
			Dystonia	54	0	34
			Opisthotonus	3	0	2
			Cogwheel rigidity	11	0	5
			Masked facies	2	0	1
			Parkinsonian gait	2	0	1
			Parkinsonism	13	1	7
			Tremor	31	0	14
			Hyperreflexia	2	0	0
			Hyporeflexia	1	0	0
			Ataxia	5	0	4
			Balance disorder	4	0	4
			Coordination abnormal	2	0	1
			Coma	2	0	0
			Aphasia	2	0	1
			Consciousness fluctuating	11	1	8
			Depressed level of consciousness	3	1	2
			Lethargy	5	0	3
			Loss of consciousness	1	0	1
			Sedation	7	1	4
			Somnolence	17	0	12
			Stupor	2	1	1
			Syncope	7	0	7
			Clonus	2	0	0
			Dizziness	24	0	14
			Drooling	4	0	3
			Meningism	1	0	1
			Myoclonus	3	0	1
			Crying	1	0	1
			Paraesthesia	2	0	2
			Ageusia	1	0	1
			Hypoaesthesia	4	0	3
			Restless legs syndrome	3	0	2

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Nervous system disorders	Sensory disturbance	2	0	2
			Dysarthria	12	0	6
			Dysphasia	1	0	1
			Speech disorder	7	0	4
			Drop attacks	1	0	1
			Hypertonia	33	2	13
			Hypotonia	1	0	1
			Neuroleptic malignant syndrome	53	2	27
			Serotonin syndrome	1	0	0
			Neuropathy peripheral	2	0	0
			Grand mal convulsion	5	0	4
			Simple partial seizures	1	0	1
			Convulsion	25	1	14
			Partial seizures with secondary generalisation	1	0	1
			Sleep phase rhythm disturbance	1	0	0
			Nervous system disorders	584	14	365
			Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	4	0
		Foetal hypokinesia		1	0	0
		Ectopic pregnancy		1	0	0
		Premature baby		2	0	0
		Small for dates baby		1	0	0
		Neonatal disorder		1	0	0
		Pregnancy, puerperium and perinatal conditions		10	0	2
		Psychiatric disorders	Agitation	25	1	14
			Anxiety	17	0	12
			Nervousness	1	0	1
			Neurosis	1	0	1
			Obsessive-compulsive disorder	2	0	2
			Catatonia	3	0	2
			Restlessness	8	0	7
			Tic	2	0	2
			Mutism	1	0	0
			Dysphemia	2	0	1
			Confusional state	29	1	15
			Disorientation	1	0	1
			Delirium	9	1	4
			Depression	7	0	5
			Depressed mood	5	0	2
			Depressive symptom	1	0	0
			Depersonalisation	3	0	2
			Delusion	7	0	7

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Medicine	Reaction Count	Psychiatric disorders	Case Group	Death Outcomes	Sole
		Hallucination	12	0	8
		Hallucination, auditory	1	0	1
		Hallucination, visual	1	0	1
		Thinking abnormal	6	0	3
		Hypomania	1	0	0
		Mania	2	0	0
		Affect lability	2	0	1
		Flat affect	3	0	3
		Anger	3	0	2
		Elevated mood	1	0	0
		Emotional distress	1	0	1
		Euphoric mood	1	0	1
		Frustration	1	0	0
		Mood swings	1	0	1
		Apathy	1	0	1
		Aggression	16	0	11
		Disinhibition	1	0	0
		Homicidal ideation	5	0	1
		Paranoia	2	0	2
		Personality change	1	0	1
		Social avoidant behaviour	1	0	1
		Violence-related symptom	1	0	0
		Abnormal behaviour	2	1	0
		Staring	1	0	0
		Mental disorder	2	0	0
		Alcohol abuse	1	0	1
		Intentional drug misuse	1	0	1
		Withdrawal syndrome	5	0	5
		Psychotic disorder	10	0	6
		Schizophrenia	1	0	1
		Anorgasmia	1	0	1
		Libido decreased	1	0	1
		Loss of libido	2	0	2
		Insomnia	15	0	9
		Abnormal dreams	1	0	1
		Nightmare	3	0	1
		Sleep disorder	1	0	0
		Completed suicide	5	5	3
		Self injurious behaviour	2	0	1
		Suicidal ideation	17	0	9
		Suicide attempt	8	0	3
		Psychiatric disorders	267	9	162

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Renal and urinary disorders	Tubulointerstitial nephritis	1	0	0
			Renal failure	1	0	0
			Renal failure acute	4	0	1
			Renal impairment	6	1	3
			Dysuria	1	0	1
			Incontinence	1	0	0
			Micturition disorder	1	0	0
			Pollakiuria	1	0	0
			Urinary incontinence	13	0	8
			Urinary retention	3	0	2
			Glycosuria	1	0	1
			Haematuria	1	0	1
			Ketonuria	1	0	1
			Myoglobinuria	1	0	0
			Polyuria	2	0	1
			Nephrolithiasis	1	0	1
			Renal and urinary disorders	39	1	20
			Reproductive system and breast disorders	Breast enlargement	4	0
		Breast mass		1	0	1
		Gynaecomastia		8	0	7
		Breast discharge		1	0	1
		Breast engorgement		1	0	1
		Breast pain		6	0	4
		Breast tenderness		1	0	1
		Nipple exudate bloody		1	0	1
		Galactorrhoea		35	0	27
		Lactation disorder		2	0	2
		Menstrual disorder		4	0	4
		Menstruation irregular		2	0	1
		Metrorrhagia		1	0	1
		Amenorrhoea		23	0	19
		Menorrhagia		1	0	1
		Polycystic ovaries		1	0	0
		Genital ulceration		1	0	0
		Oedema genital		1	0	1
		Ejaculation disorder		1	0	0
		Ejaculation failure		8	0	8
		Erectile dysfunction		5	0	4
		Priapism		9	0	9
		Infertility	2	0	2	
Sexual dysfunction	3	0	3			
Testicular disorder	2	0	1			

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Reproductive system and breast disorders	Testicular pain	1	0	1
			Reproductive system and breast disorders	125	0	102
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	2	0	1
			Wheezing	1	0	1
			Pneumonia aspiration	1	0	0
			Pulmonary oedema	2	2	1
			Pulmonary embolism	4	0	4
			Apnoea	1	0	0
			Dyspnoea	24	0	15
			Hyperventilation	1	0	1
			Hypoventilation	2	0	1
			Respiratory arrest	1	0	0
			Respiratory depression	4	0	1
			Respiratory distress	1	0	0
			Tachypnoea	1	0	1
			Haemoptysis	1	0	1
			Respiratory failure	2	2	1
			Respiratory disorder	1	0	1
			Choking	3	0	2
			Oropharyngeal pain	2	0	1
			Rhinorrhoea	1	0	1
			Throat tightness	2	0	2
			Stridor	1	0	1
			Nasal congestion	1	0	0
			Epistaxis	5	0	5
			Pharyngeal oedema	1	0	1
			Respiratory, thoracic and mediastinal disorders	65	4	42
		Skin and subcutaneous tissue disorders	Angioedema	7	0	5
			Periorbital oedema	6	0	4
			Urticaria	11	0	8
			Lichenoid keratosis	1	0	1
			Skin striae	1	0	1
			Dermatitis bullous	1	0	1
			Erythema multiforme	1	0	0
			Dry skin	2	0	2
			Skin discolouration	1	0	1
			Skin disorder	1	0	0
			Skin odour abnormal	2	0	0
			Swelling face	4	0	3
			Dermatitis	1	0	1
			Eczema	1	0	1

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			Case Group	Death Outcomes	Sole		
Medicine	Reaction Count	Skin and subcutaneous tissue disorders	Erythema	3	0	1	
			Rash erythematous	4	0	4	
			Skin exfoliation	4	0	2	
			Rash papular	1	0	1	
			Photosensitivity reaction	1	0	0	
			Pruritus	16	0	11	
			Rash pruritic	3	0	0	
			Psoriasis	2	0	1	
			Rash	24	0	15	
			Rash generalised	1	0	1	
			Rash macular	2	0	0	
			Rash maculo-papular	5	0	3	
			Skin hyperpigmentation	1	0	0	
			Skin hypopigmentation	1	0	1	
			Alopecia	5	0	4	
			Cold sweat	1	0	0	
			Hyperhidrosis	7	0	3	
			Hirsutism	1	0	0	
			Hypertrichosis	1	0	0	
			Hair texture abnormal	1	0	0	
			Seborrhoea	1	0	1	
			Purpura	2	0	0	
			Livedo reticularis	1	0	1	
		Skin and subcutaneous tissue disorders	128	0	77		
		Social circumstances	Treatment noncompliance	1	0	0	
			Social circumstances	1	0	0	
		Surgical and medical procedures	Therapy regimen changed	17	0	8	
			Surgical and medical procedures	17	0	8	
		Vascular disorders	Infarction	1	0	1	
			Blood pressure fluctuation	1	0	0	
			Circulatory collapse	8	1	6	
			Hypotension	17	0	8	
			Orthostatic hypotension	15	1	12	
			Thrombosis	1	0	1	
			Deep vein thrombosis	2	0	2	
			Flushing	6	0	3	
			Hot flush	2	0	2	
			Pallor	1	0	1	
			Hypertension	3	0	1	
			Vascular disorders	57	2	37	
		Reaction			2299	69	1429