

quetiapine to end January 2009

				Case Group	Death Outcomes	Sole
Case Count				439	14	278
Medicine	Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	1
			Thrombocytopenia	7	0	4
			Leukocytosis	3	0	2
			Lymphocytosis	1	0	0
			Neutrophilia	2	0	0
			Leukopenia	13	0	11
			Lymphopenia	1	0	1
			Agranulocytosis	1	0	0
			Neutropenia	31	1	22
			Blood and lymphatic system disorders	60	1	41
		Cardiac disorders	Bradycardia	2	0	0
			Tachycardia	22	0	11
			Atrial fibrillation	2	0	0
			Sinus tachycardia	3	0	1
			Cardiac arrest	1	0	1
			Ventricular extrasystoles	1	0	1
			Ventricular tachycardia	1	0	1
			Palpitations	3	0	2
			Myocardial infarction	2	1	1
			Cardiac failure	1	0	1
			Cardiomyopathy	5	0	2
			Ischaemic cardiomyopathy	1	0	1
			Left ventricular dysfunction	1	0	0
			Myocarditis	5	1	1
			Cardiac disorders	50	2	23
		Congenital, familial and genetic disorders	Meningomyelocele	1	0	0
			Spina bifida	1	0	0
			Congenital, familial and genetic disorders	2	0	0
		Endocrine disorders	Hyperprolactinaemia	2	0	2
			Endocrine disorders	2	0	2
		Eye disorders	Xerophthalmia	1	0	1
			Eye pain	1	0	1
			Conjunctivitis	1	0	1
			Ulcerative keratitis	1	0	1
			Blepharospasm	2	0	1
			Oculogyric crisis	2	0	1
			Mydriasis	1	0	1
			Accommodation disorder	1	0	0
			Hypermetropia	1	0	1
			Vision blurred	2	0	0
		Visual impairment	4	0	3	

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Eye disorders	Eye disorders	17	0	11
		Gastrointestinal disorders	Tooth disorder	1	0	0
			Gastrointestinal haemorrhage	1	0	1
			Melaena	1	0	0
			Gastritis	1	0	0
			Oesophagitis	1	0	0
			Diarrhoea	9	0	5
			Colonic pseudo-obstruction	1	0	1
			Constipation	10	0	10
			Dyspepsia	1	0	1
			Faecaloma	1	0	1
			Abdominal distension	2	0	1
			Abdominal pain	2	0	2
			Dysphagia	4	0	3
			Nausea	11	0	8
			Vomiting	11	0	7
			Intestinal obstruction	2	0	1
			Gastric ulcer	1	0	0
			Paraesthesia oral	1	0	1
			Hypoaesthesia oral	1	0	1
			Gingival swelling	1	0	1
			Mouth ulceration	2	0	2
			Stomatitis	1	0	1
			Dry mouth	8	0	5
			Salivary hypersecretion	1	0	0
			Swollen tongue	1	0	0
			Tongue discolouration	1	0	1
			Tongue oedema	2	0	2
			Gastrointestinal disorders	79	0	55
		General disorders and administration site conditions	Hypothermia	2	0	0
			Pyrexia	16	0	2
			Death	3	3	1
			Sudden death	5	4	0
			Asthenia	4	0	3
			Fatigue	6	1	3
			Malaise	6	1	3
			Abasia	2	0	0
			Condition aggravated	4	0	2
			Influenza like illness	2	0	2
			Irritability	1	0	1
			Face oedema	1	0	1
			Generalised oedema	2	0	1

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	General disorders and administration site conditions	Gravitational oedema	2	0	1
			Oedema	4	0	2
			Oedema peripheral	6	0	5
			Pitting oedema	2	0	2
			Chest pain	3	0	1
			Pain	2	0	1
			Chest discomfort	1	0	1
			Chills	2	0	0
			Thirst	2	0	2
			Drug interaction	4	0	0
			Drug ineffective	10	0	9
			Therapeutic response unexpected	1	0	1
			Drug withdrawal syndrome	3	0	0
			Drug withdrawal syndrome neonatal	1	0	1
			General disorders and administration site conditions	97	9	45
		Hepatobiliary disorders	Hyperbilirubinaemia	1	0	1
			Jaundice	2	0	2
			Hepatic function abnormal	5	1	4
			Hepatic failure	1	0	1
			Hepatic steatosis	4	0	3
			Hepatitis	2	0	1
			Hepatocellular injury	1	0	1
			Hepatotoxicity	1	0	1
			Hepatobiliary disorders	17	1	14
		Immune system disorders	Anaphylactic shock	1	0	1
			Immune system disorders	1	0	1
		Infections and infestations	Candidiasis	3	0	1
			Endocarditis	1	0	1
			Infection	1	0	0
			Pneumonia	1	0	0
			Pneumonia primary atypical	1	0	0
			Sepsis	1	0	0
			Rhinitis	1	0	1
			Sinusitis	1	0	1
			Influenza	1	0	0
			Infections and infestations	11	0	4
		Injury, poisoning and procedural complications	Drug exposure during pregnancy	2	1	1
			Fall	1	0	1
			Medication error	2	0	0
			Drug exposure via breast milk	1	0	1
			Accidental overdose	3	0	1
			Intentional overdose	4	1	2

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Medicine	Reaction Count	Injury, poisoning and procedural complications	Overdose	Case Group	Death Outcomes	Sole
			Overdose	5	0	2
			Injury, poisoning and procedural complications	18	2	8
		Investigations	Ejection fraction decreased	1	0	0
			Electrocardiogram QT prolonged	9	0	5
			Electrocardiogram ST segment elevation	1	0	1
			Electrocardiogram abnormal	6	0	3
			Heart rate decreased	1	0	1
			Heart rate increased	1	0	0
			Heart rate irregular	2	0	1
			Blood prolactin increased	2	0	1
			Blood thyroid stimulating hormone increased	1	0	1
			Blood creatine phosphokinase increased	16	0	5
			Cardiac enzymes increased	1	0	1
			Troponin I increased	1	0	0
			Troponin increased	1	0	0
			International normalised ratio decreased	1	0	0
			International normalised ratio increased	1	0	1
			Prothrombin level decreased	1	1	0
			Prothrombin level increased	1	0	0
			Red blood cell sedimentation rate increased	1	0	0
			Neutrophil count decreased	1	0	1
			Neutrophil count increased	3	0	0
			White blood cell count decreased	4	0	4
			White blood cell count increased	4	0	1
			Ammonia increased	1	0	0
			Hepatic enzyme increased	2	0	0
			Liver function test abnormal	2	0	0
			Antinuclear antibody positive	1	0	1
			Blood cholesterol increased	4	0	2
			Blood triglycerides increased	3	0	2
			Blood glucose fluctuation	1	0	1
			Blood glucose increased	2	0	1
			Weight decreased	4	1	3
			Weight increased	21	0	16
			C-reactive protein increased	1	0	0
			Blood creatinine increased	1	0	0
			Urine analysis abnormal	1	0	1
			Urine output decreased	1	0	1

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole	
			Drug level increased	4	0	0
			Serum ferritin increased	1	0	1
			Investigations	110	2	55
		Metabolism and nutrition disorders	Acidosis	1	0	0
			Anorexia	2	0	1
			Hypophagia	1	0	0
			Increased appetite	2	0	2
			Feeding disorder neonatal	1	0	1
			Weight loss poor	1	0	1
			Hypomagnesaemia	1	0	1
			Diabetic ketoacidosis	2	0	1
			Polydipsia	2	0	2
			Hyperkalaemia	2	0	0
			Hypokalaemia	2	0	2
			Hypernatraemia	1	0	0
			Hyponatraemia	2	0	2
			Dehydration	2	0	2
			Fluid retention	2	0	1
			Diabetes mellitus	8	0	5
			Diabetes mellitus inadequate control	1	0	1
			Type 1 diabetes mellitus	1	0	1
			Hyperglycaemia	9	0	7
			Insulin resistance	1	0	1
			Hypercholesterolaemia	1	0	1
			Metabolism and nutrition disorders	45	0	32
		Musculoskeletal and connective tissue disorders	Jaw disorder	1	0	1
			Arthritis	1	0	1
			Arthropathy	1	0	1
			Chondromalacia	1	0	1
			Arthralgia	1	0	1
			Myalgia	4	0	3
			Muscle spasms	4	0	2
			Muscle twitching	1	0	1
			Muscle rigidity	2	0	0
			Nuchal rigidity	1	0	1
			Torticollis	1	0	0
			Trismus	1	0	1
			Rhabdomyolysis	1	0	0
			Mobility decreased	3	0	0
			Musculoskeletal stiffness	1	0	1
			Posture abnormal	1	0	1
			Neck mass	1	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole		
		Musculoskeletal and connective tissue disorders	Back pain	1	0	1	
			Pain in extremity	1	0	1	
			Musculoskeletal and connective tissue disorders	28	0	18	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	1	0	1	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0	1	
			Nervous system disorders	Cerebrovascular disorder	2	0	2
				Tongue paralysis	1	0	0
				Headache	6	0	4
				Tension headache	1	0	0
				Migraine	1	0	0
				Dementia	1	0	0
				Amnesia	5	0	3
				Memory impairment	1	0	0
				Cognitive disorder	1	0	0
				Disturbance in attention	2	0	1
				Choreoathetosis	1	0	1
				Akathisia	7	0	6
				Dyskinesia	16	0	9
				Extrapyramidal disorder	4	0	4
				Hyperkinesia	4	0	4
				Movement disorder	1	0	0
				Psychomotor hyperactivity	1	0	1
				Tardive dyskinesia	17	0	13
				Dystonia	16	0	11
				Paralysis	1	0	1
				Cogwheel rigidity	1	0	0
				Parkinsonism	3	0	1
				Asterixis	1	0	1
				Tremor	6	0	2
				Hyperreflexia	1	0	0
				Coordination abnormal	3	0	1
				Nystagmus	1	0	1
				Coma	2	1	0
				Aphasia	2	0	2
				Consciousness fluctuating	1	0	0
				Depressed level of consciousness	6	0	2
				Lethargy	3	0	2
				Loss of consciousness	5	0	3
				Sedation	3	0	2
				Somnolence	18	0	11
				Syncope	6	0	4

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Nervous system disorders	Clonus	1	0	0
			Dizziness	15	0	10
			Myoclonus	1	0	1
			Presyncope	1	0	0
			Tongue biting	1	0	0
			Paraesthesia	5	0	5
			Dysgeusia	1	0	1
			Hypoaesthesia	1	0	1
			Dysarthria	3	0	2
			Dysphasia	2	0	1
			Speech disorder	3	0	0
			Visual field defect	1	0	1
			Anticholinergic syndrome	1	0	1
			Autonomic nervous system imbalance	1	0	0
			Hypertonia	7	0	4
			Neuroleptic malignant syndrome	24	0	9
			Serotonin syndrome	3	0	1
			Grand mal convulsion	4	0	1
			Convulsion	12	0	5
			Hypersomnia	1	0	1
		Nervous system disorders	239	1	136	
		Pregnancy, puerperium and perinatal conditions	Intra-uterine death	1	1	0
			Stillbirth	1	1	0
			Premature labour	1	0	0
			Pregnancy, puerperium and perinatal conditions	3	2	0
		Psychiatric disorders	Agitation	12	0	5
			Anxiety	7	0	4
			Nervousness	1	0	0
			Stress	1	1	0
			Fear	2	0	1
			Panic attack	2	0	2
			Panic disorder	1	0	0
			Neurosis	2	0	2
			Compulsions	1	0	1
			Obsessive-compulsive disorder	1	0	0
			Catatonia	1	0	1
			Restlessness	3	0	1
			Bruxism	1	0	0
			Stereotypy	1	0	1
			Tic	1	0	0
			Mutism	1	0	1
		Dysphemia	2	0	1	

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Psychiatric disorders	Poverty of speech	1	0	1
			Confusional state	17	0	6
			Disorientation	1	0	0
			Delirium	9	0	3
			Depression	6	1	1
			Feeling of despair	1	0	0
			Depersonalisation	2	0	1
			Delusion	3	0	2
			Hallucination	8	0	5
			Hallucination, auditory	3	0	1
			Thinking abnormal	2	0	1
			Mania	3	0	0
			Affect lability	2	0	1
			Anger	1	0	0
			Emotional disorder	1	0	0
			Mood swings	1	0	0
			Aggression	7	0	4
			Homicidal ideation	4	0	3
			Paranoia	2	1	1
			Personality change	1	0	1
			Abnormal behaviour	4	0	2
			Mental status changes	1	0	1
			Drug dependence	1	0	1
			Intentional drug misuse	1	0	1
			Withdrawal syndrome	4	0	2
			Psychotic disorder	10	0	6
			Schizophreniform disorder	1	0	0
			Schizophrenia	2	0	2
			Insomnia	4	0	2
			Sleep terror	1	0	0
			Somnambulism	1	0	0
			Sleep disorder	1	0	0
			Completed suicide	3	3	2
			Self injurious behaviour	2	0	1
			Suicidal ideation	12	0	5
			Suicide attempt	7	0	3
			Psychiatric disorders	170	6	79
		Renal and urinary disorders	Anuria	1	0	0
			Renal failure acute	2	0	0
			Renal impairment	1	0	0
			Azotaemia	1	0	0
			Dysuria	1	0	1

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Renal and urinary disorders	Urinary retention	11	0	8
			Urine flow decreased	1	0	0
			Glycosuria	1	0	1
			Ketonuria	2	0	2
			Polyuria	3	0	2
			Renal and urinary disorders	24	0	14
		Reproductive system and breast disorders	Gynaecomastia	1	0	0
			Galactorrhoea	3	0	1
			Cervix disorder	1	0	1
			Amenorrhoea	2	0	0
			Genital pain	1	0	0
			Priapism	4	0	3
			Testicular retraction	1	0	0
			Vaginal ulceration	1	0	1
			Reproductive system and breast disorders	14	0	6
		Respiratory, thoracic and mediastinal disorders	Asthma	1	0	0
			Wheezing	1	0	1
			Infantile apnoeic attack	1	0	0
			Cheyne-Stokes respiration	1	0	1
			Dyspnoea	10	0	5
			Hypoventilation	1	0	1
			Sleep apnoea syndrome	1	0	0
			Tachypnoea	1	0	0
			Cough	1	0	0
			Pleuritic pain	1	0	0
			Respiratory failure	1	1	1
			Oropharyngeal blistering	1	0	1
			Oropharyngeal pain	1	0	0
			Throat tightness	1	0	1
			Nasal congestion	2	0	1
			Respiratory, thoracic and mediastinal disorders	25	1	12
			Skin and subcutaneous tissue disorders	Angioedema	1	0
		Periorbital oedema		1	0	1
		Urticaria		4	0	3
		Dermatitis bullous		1	1	0
		Erythema multiforme		1	0	0
		Stevens-Johnson syndrome		1	0	0
		Toxic epidermal necrolysis		1	0	0
		Skin discolouration		2	0	1
		Erythema		3	0	1
		Dermatitis exfoliative		1	0	0

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			Case Group	Death Outcomes	Sole		
Medicine	Reaction Count	Skin and subcutaneous tissue disorders	Skin exfoliation	1	0	0	
			Photosensitivity reaction	2	0	2	
			Pruritus	5	0	4	
			Psoriasis	2	0	1	
			Rash	7	0	6	
			Rash macular	1	0	0	
			Rash maculo-papular	3	0	3	
			Alopecia	3	0	3	
			Hyperhidrosis	10	0	2	
			Night sweats	1	0	0	
			Nail discolouration	1	0	0	
			Nail disorder	1	0	0	
			Purpura	1	1	0	
			Haemorrhage subcutaneous	1	0	0	
			Skin and subcutaneous tissue disorders	55	2	28	
		Social circumstances	Treatment noncompliance	1	0	0	
			Social circumstances	1	0	0	
		Surgical and medical procedures	Therapy regimen changed	8	0	5	
			Surgical and medical procedures	8	0	5	
		Vascular disorders	Peripheral ischaemia	1	0	0	
			Poor peripheral circulation	1	0	0	
			Blood pressure fluctuation	1	0	1	
			Circulatory collapse	6	0	2	
			Shock	1	0	0	
			Hypotension	13	0	6	
			Orthostatic hypotension	5	0	3	
			Deep vein thrombosis	1	0	0	
			Flushing	3	0	1	
			Pallor	1	0	1	
			Hypertension	3	0	2	
		Vascular disorders	36	0	16		
		Reaction			1113	29	606