

Medicine summary - Antipsychotics- quetiapine

		Case Group	Death Outcomes	Sole
Case Count		626	27	369
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	0
		Thrombocytopenia	9	0
		Polycythaemia	1	0
		Leukocytosis	3	0
		Lymphocytosis	1	0
		Neutrophilia	2	0
		Leukopenia	15	0
		Lymphopenia	1	0
		Agranulocytosis	1	0
		Neutropenia	38	1
		Blood and lymphatic system disorders	73	1
			44	
	Cardiac disorders	Atrioventricular block first degree	1	0
		Bundle branch block left	1	0
		Arrhythmia	1	0
		Bradycardia	3	0
		Tachycardia	27	0
		Atrial fibrillation	2	0
		Sinus tachycardia	3	0
		Cardiac arrest	1	0
		Cardio-respiratory arrest	1	1
		Torsade de pointes	1	0
		Ventricular extrasystoles	1	0
		Ventricular tachycardia	2	0
		Palpitations	8	0
		Myocardial infarction	3	1
		Myocardial ischaemia	1	1
		Cardiac failure	1	0
		Cardiomyopathy	6	0
		Ischaemic cardiomyopathy	2	0
		Diastolic dysfunction	1	0
		Left ventricular dysfunction	1	0
		Myocarditis	6	1

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Reaction Count			Case Group	Death Outcomes	Sole
	Cardiac disorders	Cardiac disorders	73	4	35
	Congenital, familial and genetic disorders	Pulmonary artery atresia	1	0	0
		Ventricular septal defect	1	0	0
		Meningomyelocele	1	0	0
		Spina bifida	1	0	0
		Congenital, familial and genetic disorders	4	0	0
	Ear and labyrinth disorders	Deafness	1	0	0
		Vertigo	1	0	0
		Ear and labyrinth 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
		Periorbital oedema	1	0	1
		Conjunctivitis	1	0	1
		Ulcerative keratitis	1	0	1
		Blepharospasm	2	0	1
		Oculogyric crisis	4	0	1
		Opsclonus myoclonus	1	0	1
		Mydriasis	3	0	1
		Accommodation disorder	1	0	0
		Hypermetropia	1	0	1
		Vision blurred	2	0	0
		Visual impairment	4	0	3
		Eye disorders	23	0	13
	Gastrointestinal disorders	Tooth disorder	1	0	0
		Tooth loss	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

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Gastrointestinal disorders	Constipation	12 0 11
	Dyspepsia	2 0 2
	Faecaloma	2 0 1
	Abdominal distension	3 0 2
	Abdominal pain	3 0 3
	Dysphagia	7 0 4
	Nausea	14 0 9
	Vomiting	11 0 7
	Intestinal obstruction	2 0 1
	Intestinal stenosis	1 0 1
	Gastric ulcer	1 0 0
	Intestinal ulcer	1 0 1
	Paraesthesia oral	1 0 1
	Hypoesthesia oral	1 0 1
	Gingival swelling	1 0 1
	Mouth ulceration	2 0 2
	Stomatitis	1 0 1
	Dry mouth	10 0 7
	Salivary hypersecretion	1 0 0
	Tongue disorder	3 0 0
	Tongue ulceration	1 0 1
	Swollen tongue	1 0 0
	Tongue discolouration	1 0 1
	Tongue oedema	2 0 2
	Tongue spasm	1 0 1
	Gastrointestinal disorders	101 0 67
General disorders and administration site conditions	Hypothermia	3 0 1
	Pyrexia	19 0 5
	Death	6 6 2
	Sudden death	5 4 0
	Asthenia	4 0 3
	Fatigue	7 1 3
	Malaise	5 1 2

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Abasia	2	0
Gait disturbance	4	0
Condition aggravated	6	0
Influenza like illness	3	0
Irritability	3	2
Face oedema	1	0
Generalised oedema	2	0
Gravitational oedema	2	1
Oedema	6	0
Oedema peripheral	10	7
Chest pain	5	1
Pain	3	0
Chest discomfort	1	0
Chills	3	0
Feeling abnormal	2	2
Thirst	2	0
Drug interaction	13	0
Drug ineffective	13	1
Therapeutic response unexpected	1	0
Drug withdrawal syndrome	5	0
Drug withdrawal syndrome neonatal	9	0
Product quality issue	1	0
Product substitution issue	1	0
General disorders and administration site conditions	147	14
		67
Hyperbilirubinaemia	1	0
Jaundice	5	0
Hepatic function abnormal	9	1
Hepatic failure	1	0
Hepatic steatosis	3	0
Hepatitis	2	0
Hepatocellular injury	1	0
Hepatotoxicity	1	0

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			Case Group	Death Outcomes	Sole
Reaction Count	Hepatobiliary disorders	Hepatobiliary disorders	23	1	18
	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
		Urinary tract infection	2	0	1
		Influenza	1	0	0
		Viral upper respiratory tract infection	1	0	1
		Infections and infestations	14	0	6
	Injury, poisoning and procedural complications	Accidental poisoning	2	2	0
		Toxicity to various agents	3	3	0
		Drug exposure during pregnancy	26	1	15
		Fall	5	0	2
		Road traffic accident	1	0	0
		Frostbite	1	0	1
		Incorrect dose administered	1	0	0
		Medication error	2	0	0
		Drug exposure via breast milk	3	0	1
		Accidental overdose	4	1	1
		Intentional overdose	8	1	4
		Multiple drug overdose	1	0	0
		Overdose	8	1	3
		Injury, poisoning and procedural complications	65	9	27
	Investigations	Ejection fraction decreased	2	0	1
		Cardiovascular function test abnormal	1	0	0
		Electrocardiogram QT prolonged	15	0	9
		Electrocardiogram ST segment elevation	1	0	1

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	Electrocardiogram abnormal	6	0	3
	Heart rate decreased	1	0	1
	Heart rate increased	2	0	1
	Heart rate irregular	3	0	2
	Blood prolactin increased	4	0	2
	Blood thyroid stimulating hormone increased	1	0	1
	Blood creatine phosphokinase increased	22	0	8
	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
	Lymphocyte count increased	1	0	1
	Neutrophil count decreased	1	0	1
	Neutrophil count increased	3	0	0
	White blood cell count decreased	5	0	4
	White blood cell count increased	5	0	2
	Ammonia increased	1	0	0
	Hepatic enzyme increased	2	0	0
	Liver function test abnormal	3	0	1
	Antinuclear antibody positive	1	0	1
	Blood cholesterol increased	5	0	3
	Blood triglycerides increased	4	0	3
	Blood glucose decreased	1	0	1
	Blood glucose fluctuation	1	0	1
	Blood glucose increased	2	0	1
	Coma scale abnormal	1	0	1
	Corneal reflex decreased	1	0	0
	Body temperature increased	1	0	1
	Weight decreased	6	1	3

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	Investigations	Weight increased	26	0	20
		C-reactive protein increased	2	0	1
		Blood chromogranin A increased	1	0	1
		Protein albumin ratio	1	0	1
		Blood creatinine increased	2	0	1
		Glomerular filtration rate decreased	2	0	1
		Urine analysis abnormal	1	0	1
		Urine output decreased	1	0	1
		Drug level increased	4	0	0
		Chemotherapeutic drug level above therapeutic	1	0	0
		Serum ferritin increased	1	0	1
		Investigations	152	2	83
	Metabolism and nutrition disorders	Ketosis	1	0	1
		Acidosis	2	0	0
		Decreased appetite	2	0	1
		Hypophagia	1	0	0
		Increased appetite	2	0	2
		Feeding disorder neonatal	2	0	2
		Weight loss poor	1	0	1
		Hypomagnesaemia	2	0	1
		Diabetic ketoacidosis	2	0	1
		Hyperosmolar state	1	0	1
		Polydipsia	2	0	2
		Hyperkalaemia	2	0	0
		Hypokalaemia	4	0	3
		Hypernatraemia	1	0	0
		Hyponatraemia	4	0	3
		Dehydration	2	0	2
		Fluid retention	2	0	1
		Diabetes mellitus	9	0	5
		Diabetes mellitus inadequate control	1	0	1
		Gestational diabetes	3	0	3
		Type 1 diabetes mellitus	1	0	1

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	Metabolism and nutrition disorders	Hyperglycaemia	10	0	8
		Insulin resistance	2	0	2
		Hypercholesterolaemia	2	0	2
		Metabolism and nutrition disorders	61	0	43
	Musculoskeletal and connective tissue disorders	Jaw disorder	1	0	1
		Bone loss	1	0	0
		Arthritis	1	0	1
		Arthropathy	1	0	1
		Chondromalacia	1	0	1
		Arthralgia	2	0	2
		Joint stiffness	1	0	1
		Joint swelling	1	0	1
		Myalgia	6	0	5
		Muscle spasms	4	0	2
		Muscle twitching	3	0	1
		Muscle rigidity	6	0	1
		Nuchal rigidity	1	0	1
		Torticollis	1	0	0
		Trismus	3	0	1
		Muscular weakness	1	0	1
		Rhabdomyolysis	2	0	0
		Mobility decreased	5	0	0
		Musculoskeletal stiffness	3	0	3
		Posture abnormal	1	0	1
		Neck mass	1	0	1
		Back pain	1	0	1
		Pain in extremity	2	0	2
		Musculoskeletal and connective tissue disorders	49	0	28
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	1	0	1
		Acute lymphocytic leukaemia	1	0	0
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0	1
	Nervous system disorders	Cerebral haemorrhage	1	1	0

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Cerebrovascular disorder	2	0	2
Tongue paralysis	1	0	0
Headache	10	2	6
Tension headache	1	0	0
Migraine	1	0	0
Hydrocephalus	1	0	1
Dementia	2	0	1
Amnesia	9	0	5
Memory impairment	1	0	0
Cognitive disorder	1	0	0
Disturbance in attention	3	0	2
Mental impairment	1	0	0
Choreoathetosis	1	0	1
Akathisia	10	1	8
Dyskinesia	18	0	11
Extrapyramidal disorder	4	0	4
Hyperkinesia	4	0	4
Movement disorder	2	0	0
Psychomotor hyperactivity	1	0	1
Tardive dyskinesia	18	0	14
Dystonia	16	0	11
Spasmodic dysphonia	1	0	0
Paralysis	1	0	1
Cogwheel rigidity	1	0	0
Parkinsonism	4	0	1
Asterixis	1	0	1
Tremor	15	0	6
Hyperreflexia	2	0	0
Ataxia	2	0	1
Coordination abnormal	3	0	1
Nystagmus	2	0	1
Coma	2	1	0
Aphasia	4	0	3

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Reaction Count	Nervous system disorders	Altered state of consciousness	1	0	0
		Consciousness fluctuating	1	0	0
		Depressed level of consciousness	5	0	2
		Lethargy	5	1	3
		Loss of consciousness	9	0	4
		Sedation	6	1	3
		Somnolence	21	2	11
		Syncope	6	0	4
		Clonus	3	0	0
		Dizziness	20	0	13
		Drooling	1	0	1
		Myoclonus	3	0	2
		Presyncope	1	0	0
		Tongue biting	1	0	0
		Unresponsive to stimuli	1	0	0
		Paraesthesia	5	0	5
		Aura	1	0	0
		Dysgeusia	1	0	1
		Hypoesthesia	1	0	1
		Restless legs syndrome	1	0	1
		Dysarthria	8	0	4
		Speech disorder	4	0	1
		Visual field defect	1	0	1
		Anticholinergic syndrome	1	0	1
		Autonomic nervous system imbalance	1	0	0
		Hypertonia	7	0	4
		Hypotonia	1	0	1
		Neuroleptic malignant syndrome	33	0	11
		Serotonin syndrome	7	2	1
		Mononeuropathy	1	0	0
		Nerve compression	1	0	0
		Neuropathy peripheral	1	0	0
		Brachial plexopathy	1	0	0

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		Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders Pregnancy, puerperium and perinatal conditions Psychiatric disorders	Petit mal epilepsy Grand mal convolution Convulsion Epilepsy Hypersomnia Nervous system disorders	1 6 20 1 2 336	0 0 2 0 0 13 174
		Abortion spontaneous Intra-uterine death Stillbirth Foetal distress syndrome Premature labour Hyperemesis gravidarum Premature baby Jaundice neonatal Placenta praevia Postpartum haemorrhage Pregnancy, puerperium and perinatal conditions	5 1 1 1 1 1 4 1 1 1 17	0 1 1 0 0 0 0 0 0 2 6
		Agitation Anxiety Nervousness Stress Fear Panic attack Panic disorder Neurosis Compulsions Obsessive-compulsive disorder Catatonia Restlessness Bruxism Stereotypy Tic	15 10 1 1 2 2 1 2 1 2 1 3 1 1 1 1	0 0 0 1 0 0 0 0 0 0 0 0 0 0 0

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Reaction Count	Psychiatric disorders	Case Group	Death Outcomes	Sole
	Mutism	1	0	1
	Dysphemia	2	0	1
	Poverty of speech	1	0	1
	Confusional state	21	1	8
	Disorientation	1	0	0
	Delirium	9	0	4
	Depression	7	1	2
	Postpartum depression	1	0	1
	Feeling of despair	1	0	0
	Depersonalisation	2	0	1
	Dissociation	1	0	0
	Dissociative disorder	1	0	1
	Delusion	5	0	4
	Deja vu	1	0	0
	Hallucination	8	0	5
	Hallucination, auditory	3	0	1
	Thinking abnormal	2	0	1
	Mania	4	0	1
	Affect lability	2	0	1
	Anger	2	0	0
	Emotional disorder	1	0	0
	Mood swings	1	0	0
	Aggression	9	1	4
	Homicidal ideation	4	0	3
	Paranoia	4	1	2
	Personality change	1	0	1
	Self esteem decreased	1	0	0
	Abnormal behaviour	5	0	2
	Mental disorder	1	0	0
	Mental status changes	2	0	2
	Dependence	1	0	0
	Drug abuse	1	0	1
	Drug dependence	4	0	3

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Reaction Count			Case Group	Death Outcomes	Sole
	Psychiatric disorders	Intentional drug misuse	1	0	1
		Withdrawal syndrome	8	0	5
		Psychotic disorder	13	0	7
		Schizophreniform disorder	1	0	0
		Schizophrenia	3	0	2
		Insomnia	7	0	3
		Abnormal dreams	1	0	0
		Abnormal sleep-related event	4	0	2
		Nightmare	1	0	1
		Sleep terror	1	0	0
		Somnambulism	5	0	2
		Sleep disorder	1	0	0
		Completed suicide	4	4	2
		Self injurious behaviour	2	0	1
		Self-injurious ideation	1	0	1
		Suicidal ideation	16	0	8
		Suicide attempt	8	0	3
		Psychiatric disorders	231	9	113
	Renal and urinary disorders	Anuria	1	0	0
		Renal failure acute	3	0	0
		Renal impairment	3	0	0
		Azotaemia	1	0	0
		Dysuria	2	0	2
		Enuresis	1	0	1
		Incontinence	1	0	1
		Urinary retention	14	0	10
		Urine flow decreased	1	0	0
		Glycosuria	1	0	1
		Ketonuria	2	0	2
		Polyuria	3	0	2
		Renal and urinary disorders	33	0	19
	Reproductive system and breast disorders	Breast mass	1	0	1
		Gynaecomastia	1	0	0

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Reaction Count	Reproductive system and breast disorders	Breast tenderness	1	0	1
		Galactorrhoea	3	0	1
		Cervix disorder	1	0	1
		Menstruation irregular	1	0	1
		Amenorrhoea	2	0	0
		Genital pain	1	0	0
		Priapism	5	0	4
		Dyspareunia	1	0	1
		Infertility female	1	0	1
		Testicular retraction	1	0	0
		Uterine cyst	1	0	1
		Vaginal ulceration	1	0	1
		Reproductive system and breast disorders	21	0	13
Respiratory, thoracic and mediastinal disorders	Respiratory, thoracic and mediastinal disorders	Asthma	1	0	0
		Wheezing	1	0	1
		Pneumonia aspiration	1	0	0
		Infantile apnoeic attack	1	0	0
		Neonatal respiratory distress syndrome	4	0	1
		Neonatal respiratory failure	1	0	0
		Cheyne-Stokes respiration	2	1	1
		Dyspnoea	11	0	6
		Hypopnoea	2	0	1
		Respiratory depression	3	3	0
		Respiratory distress	2	0	2
		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
		Sneezing	1	0	0
		Throat tightness	1	0	1

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	Respiratory, thoracic and mediastinal disorders	Nasal congestion		2	0	1
		Respiratory, thoracic and mediastinal disorders		40	5	16
	Skin and subcutaneous tissue disorders	Angioedema		1	0	1
		Urticaria		5	0	4
		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
		Skin lesion		1	0	1
		Erythema		5	0	2
		Rash erythematous		4	0	1
		Dermatitis exfoliative		1	0	0
		Skin exfoliation		4	0	2
		Photosensitivity reaction		2	0	2
		Pruritus		5	0	4
		Nail psoriasis		1	0	1
		Psoriasis		3	0	2
		Rash		7	0	6
		Rash macular		1	0	0
		Rash maculo-papular		3	0	3
		Alopecia		2	0	2
		Hyperhidrosis		13	0	3
		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		69	2	35
	Social circumstances	Loss of employment		1	0	0
		Physical assault		1	0	0
		Treatment noncompliance		1	0	0
		Social circumstances		3	0	0

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	Surgical and medical procedures	Off label use	3	0	2
		Therapy regimen changed	8	0	5
		Self-medication	1	0	0
		Surgical and medical procedures	12	0	7
	Vascular disorders	Peripheral ischaemia	1	0	0
		Poor peripheral circulation	1	0	0
		Blood pressure fluctuation	1	0	1
		Circulatory collapse	8	0	2
		Shock	1	0	0
		Hypotension	20	0	10
		Orthostatic hypotension	7	0	5
		Deep vein thrombosis	1	0	0
		Flushing	4	0	1
		Pallor	1	0	1
		Subgaleal haematoma	1	0	1
		Hypertension	5	0	2
		Vascular disorders	51	0	23
	Reaction		1605	62	841

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