



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

QUETIAPINE		Layer 1 of 1		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		333	10	212
<b>- Occurrences of Medicine</b>		334	10	212
<b>- Reactions Related to Medicine</b>		867	17	480
Blood and lymphatic system disorders	Agranulocytosis	1	0	0
	Anaemia	1	0	1
	Leukocytosis	3	0	2
	Leukopenia	9	0	7
	Lymphopenia	1	0	1
	Neutropenia	21	1	16
	Neutrophilia	1	0	0
	Thrombocythaemia	1	0	0
	Thrombocytopenia	6	0	3
Cardiac disorders	Atrial fibrillation	1	0	0
	Bradycardia	2	0	0
	Cardiac arrest	1	0	1
	Cardiac failure	1	0	1
	Cardiomyopathy	4	0	2
	Myocardial infarction	2	1	1
	Myocarditis	5	1	1
	Palpitations	3	0	2
	Sinus tachycardia	1	0	0
	Tachycardia	14	0	7
	Ventricular tachycardia	1	0	1
Endocrine disorders	Hyperprolactinaemia	2	0	2
Eye disorders	Accommodation disorder	1	0	0
	Blepharospasm	2	0	1
	Conjunctivitis	1	0	1
	Eye pain	1	0	1
	Hypermetropia	1	0	1
	Mydriasis	1	0	1
	Oculogyration	1	0	0

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Eye disorders	Ulcerative keratitis	1	0	1
	Vision blurred	2	0	0
	Visual disturbance	4	0	3
	Xerophthalmia	1	0	1
Gastrointestinal disorders	Abdominal distension	1	0	0
	Abdominal pain	2	0	2
	Colonic pseudo-obstruction	1	0	1
	Constipation	9	0	9
	Diarrhoea	7	0	4
	Dry mouth	8	0	5
	Dyspepsia	1	0	1
	Dysphagia	3	0	2
	Faecaloma	1	0	1
	Gastric ulcer	1	0	0
	Gastritis	1	0	0
	Intestinal obstruction	2	0	1
	Melaena	1	0	0
	Mouth ulceration	2	0	2
	Nausea	10	0	8
	Oesophagitis	1	0	0
	Oral mucosal blistering	1	0	1
	Salivary hypersecretion	1	0	0
	Stomatitis	1	0	1
	Swollen tongue	1	0	0
Tongue oedema	1	0	1	
Tooth disorder	1	0	0	
Vomiting	9	0	5	
General disorders and administration site conditions	Abasia	2	0	0
	Asthenia	4	0	3
	Chest discomfort	1	0	1
	Chest pain	2	0	0
	Chills	2	0	0
	Condition aggravated	4	0	2
	Death	3	3	1
	Drug ineffective	8	0	7

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General disorders and administration site conditions	Drug interaction	4	0	0
	Drug withdrawal syndrome	5	0	0
	Drug withdrawal syndrome neonatal	1	0	1
	Face oedema	1	0	1
	Fatigue	6	1	3
	Generalised oedema	1	0	0
	Gravitational oedema	2	0	1
	Hypothermia	2	0	0
	Influenza like illness	2	0	2
	Irritability	1	0	1
	Malaise	6	1	3
	Oedema	4	0	2
	Oedema peripheral	3	0	2
	Pain	2	0	1
	Pitting oedema	1	0	1
	Pyrexia	15	0	2
	Sudden death	3	3	0
	Therapeutic response unexpected	1	0	1
	Thirst	2	0	2
Hepatobiliary disorders	Hepatic failure	1	0	1
	Hepatic function abnormal	3	1	2
	Hepatic steatosis	2	0	1
	Hepatitis	2	0	1
	Hepatocellular damage	1	0	1
	Hepatotoxicity	1	0	1
	Hyperbilirubinaemia	1	0	1
	Jaundice	2	0	2
Immune system disorders	Anaphylactic shock	1	0	1
Infections and infestations	Candidiasis	3	0	1
	Endocarditis	1	0	1
	Infection	1	0	0
	Influenza	1	0	0
	Pneumonia	1	0	0
	Pneumonia primary atypical	1	0	0
	Rhinitis	1	0	1



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Infections and infestations	Sepsis	1	0	0
	Sinusitis	1	0	1
Injury, poisoning and procedural complications	Accidental overdose	2	0	1
	Intentional drug misuse	1	0	1
	Intentional overdose	2	0	2
	Medication error	2	0	0
	Overdose	4	0	2
Investigations	Ammonia increased	1	0	0
	Antinuclear antibody positive	1	0	1
	Blood cholesterol increased	3	0	2
	Blood creatine phosphokinase increased	14	0	5
	Blood creatinine increased	1	0	0
	Blood glucose increased	1	0	1
	Blood thyroid stimulating hormone increased	1	0	1
	Blood triglycerides increased	1	0	1
	C-reactive protein increased	1	0	0
	Drug level increased	4	0	0
	Electrocardiogram abnormal	5	0	3
	Electrocardiogram QT prolonged	6	0	4
	Electrocardiogram ST segment elevation	1	0	1
	Heart rate decreased	1	0	1
	Heart rate increased	1	0	0
	Heart rate irregular	2	0	1
	Hepatic enzyme increased	2	0	0
	International normalised ratio decreased	1	0	0
	International normalised ratio increased	1	0	1
	Liver function test abnormal	2	0	0
	Neutrophil count decreased	1	0	1
	Neutrophil count increased	1	0	0
	Platelet count decreased	1	0	1
	Prothrombin level decreased	1	1	0
	Prothrombin level increased	1	0	0
	Red blood cell sedimentation rate increased	1	0	0
	Serum ferritin increased	1	0	1
	Troponin I increased	1	0	0

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Investigations	Troponin increased	1	0	0
	Urine analysis abnormal	1	0	1
	Urine output decreased	1	0	1
	Weight decreased	3	0	2
	Weight increased	12	0	10
	White blood cell count decreased	3	0	3
	White blood cell count increased	2	0	1
Metabolism and nutrition disorders	Acidosis	1	0	0
	Anorexia	2	0	1
	Dehydration	2	0	2
	Diabetes mellitus	5	0	4
	Diabetes mellitus inadequate control	1	0	1
	Diabetes mellitus insulin-dependent	1	0	1
	Diabetic ketoacidosis	2	0	1
	Feeding disorder neonatal	1	0	1
	Fluid retention	1	0	1
	Hyperglycaemia	8	0	7
	Hyperkalaemia	2	0	0
	Hypernatraemia	1	0	0
	Hypokalaemia	1	0	1
	Hyponatraemia	2	0	2
	Insulin resistance	1	0	1
Polydipsia	2	0	2	
Musculoskeletal and connective tissue disorders	Arthritis	1	0	1
	Arthropathy	1	0	1
	Back pain	1	0	1
	Chondromalacia	1	0	1
	Jaw disorder	1	0	1
	Mobility decreased	2	0	0
	Muscle rigidity	1	0	0
	Muscle spasms	4	0	2
	Musculoskeletal stiffness	1	0	1
	Myalgia	4	0	3
	Neck mass	1	0	1
	Nuchal rigidity	1	0	1

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Musculoskeletal and connective tissue disorders	Pain in extremity	1	0	1
	Rhabdomyolysis	1	0	0
	Torticollis	1	0	0
Neoplasms benign, malignant and unspecified	Breast cancer female	1	0	1
Nervous system disorders	Akathisia	7	0	6
	Amnesia	4	0	2
	Aphasia	2	0	2
	Asterixis	1	0	1
	Autonomic nervous system imbalance	1	0	0
	Cerebrovascular disorder	2	0	2
	Choreoathetosis	1	0	1
	Cognitive disorder	1	0	0
	Coma	1	0	0
	Consciousness fluctuating	1	0	0
	Convulsion	11	0	5
	Coordination abnormal	2	0	0
	Dementia	1	0	0
	Depressed level of consciousness	6	0	2
	Disturbance in attention	2	0	1
	Dizziness	15	0	10
	Dysarthria	2	0	2
	Dysgeusia	1	0	1
	Dyskinesia	14	0	9
	Dysphasia	2	0	1
	Dystonia	14	0	10
	Extrapyramidal disorder	3	0	3
	Grand mal convulsion	3	0	1
	Headache	5	0	4
	Hyperkinesia	4	0	4
	Hypertonia	7	0	4
	Hypoaesthesia	1	0	1
	Lethargy	3	0	2
	Loss of consciousness	4	0	2
	Memory impairment	1	0	0
	Migraine	1	0	0

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Nervous system disorders	Movement disorder	1	0	0
	Neuroleptic malignant syndrome	16	0	5
	Nystagmus	1	0	1
	Paraesthesia	5	0	5
	Paralysis	1	0	1
	Parkinsonism	3	0	1
	Psychomotor hyperactivity	1	0	1
	Sedation	3	0	2
	Serotonin syndrome	3	0	1
	Somnolence	16	0	10
	Speech disorder	2	0	0
	Syncope	5	0	3
	Tardive dyskinesia	8	0	5
	Tongue biting	1	0	0
	Tongue paralysis	1	0	0
	Tremor	5	0	2
	Visual field defect	1	0	1
Pregnancy, puerperium and perinatal condi	Premature labour	1	0	0
Psychiatric disorders	Abnormal behaviour	3	0	2
	Affect lability	2	0	1
	Aggression	5	0	4
	Agitation	8	0	2
	Anger	1	0	0
	Anxiety	3	0	1
	Bruxism	1	0	0
	Completed suicide	1	1	1
	Confusional state	17	0	6
	Delirium	9	0	3
	Delusion	2	0	2
	Depersonalisation	2	0	1
	Depression	3	0	1
	Disorientation	1	0	0
	Dysphemia	1	0	0
	Fear	2	0	1
	Feeling of despair	1	0	0

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Psychiatric disorders	Hallucination	6	0	4
	Hallucination, auditory	1	0	1
	Homicidal ideation	4	0	3
	Insomnia	2	0	1
	Mania	1	0	0
	Nervousness	1	0	0
	Neurosis	2	0	2
	Obsessive-compulsive disorder	1	0	0
	Panic attack	2	0	2
	Panic disorder	1	0	0
	Paranoia	1	0	1
	Personality change	1	0	1
	Poverty of speech	1	0	1
	Psychotic disorder	7	0	5
	Restlessness	1	0	1
	Schizophrenia	1	0	1
	Schizophreniform disorder	1	0	0
	Sleep disorder	1	0	0
	Sleep terror	1	0	0
	Sleep walking	1	0	0
Suicidal ideation	11	0	4	
Suicide attempt	6	0	3	
Thinking abnormal	2	0	1	
Tic	1	0	0	
Renal and urinary disorders	Anuria	1	0	0
	Azotaemia	1	0	0
	Dysuria	1	0	1
	Glycosuria	1	0	1
	Ketonuria	2	0	2
	Polyuria	3	0	2
	Renal failure acute	2	0	0
	Renal impairment	1	0	0
	Urinary retention	8	0	6
Reproductive system and breast disorders	Amenorrhoea	1	0	0
	Cervix disorder	1	0	1



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Reproductive system and breast disorders	Galactorrhoea	2	0	1
	Genital pain	1	0	0
	Priapism	3	0	2
	Testicular retraction	1	0	0
	Vaginal ulceration	1	0	1
Respiratory, thoracic and mediastinal disorders	Asthma	1	0	0
	Cheyne-Stokes respiration	1	0	1
	Cough	1	0	0
	Dyspnoea	7	0	3
	Hypoventilation	1	0	1
	Infantile apnoeic attack	1	0	0
	Nasal congestion	2	0	1
	Pharyngolaryngeal pain	1	0	0
	Pleuritic pain	1	0	0
	Respiratory failure	1	1	1
	Tachypnoea	1	0	0
	Throat tightness	1	0	1
Skin and subcutaneous tissue disorders	Alopecia	3	0	3
	Dermatitis bullous	1	1	0
	Dermatitis exfoliative	1	0	0
	Erythema	2	0	1
	Erythema multiforme	1	0	0
	Haemorrhage subcutaneous	1	0	0
	Hyperhidrosis	8	0	2
	Nail discolouration	1	0	0
	Nail disorder	1	0	0
	Night sweats	1	0	0
	Periorbital oedema	1	0	1
	Photosensitivity reaction	2	0	2
	Pruritus	4	0	4
	Psoriasis	2	0	1
	Purpura	1	1	0
	Rash	7	0	6
	Rash maculo-papular	3	0	3
Skin discolouration	2	0	1	



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Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	1	0	0
	Toxic epidermal necrolysis	1	0	0
	Urticaria	2	0	1
Surgical and medical procedures	Therapy regimen changed	5	0	3
Vascular disorders	Blood pressure fluctuation	1	0	1
	Circulatory collapse	6	0	2
	Deep vein thrombosis	1	0	0
	Flushing	3	0	1
	Hypertension	2	0	2
	Hypotension	9	0	6
	Orthostatic hypotension	3	0	2
	Peripheral ischaemia	1	0	0
	Poor peripheral circulation	1	0	0