

# THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

OLANZAPINE		Layer 1 of 1		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		1231	40	825
<b>- Occurrences of Medicine</b>		1247	41	825
<b>- Reactions Related to Medicine</b>		2677	106	1584
Blood and lymphatic system disorders	Agranulocytosis	4	0	1
	Anaemia	6	1	2
	Aplastic anaemia	2	0	2
	Bone marrow failure	2	0	2
	Eosinopenia	1	0	1
	Eosinophilia	3	0	2
	Hypochromic anaemia	6	0	6
	Leukocytosis	16	1	3
	Leukopenia	25	0	15
	Lymphocytosis	1	1	0
	Lymphopenia	3	0	2
	Monocytosis	1	0	1
	Neutropenia	55	1	30
	Neutrophilia	3	0	3
	Normochromic normocytic anaemia	1	0	0
	Pancytopenia	5	0	3
	Splenomegaly	1	0	0
	Thrombocythaemia	1	0	0
	Thrombocytopenia	10	0	4
Cardiac disorders	Arrhythmia	3	1	1
	Atrial fibrillation	5	0	4
	Atrioventricular block	1	0	1
	Bradycardia	9	1	6
	Cardiac arrest	8	6	3
	Cardiac disorder	1	0	1
	Cardiac failure	6	0	2
	Cardiac failure congestive	1	0	1
	Cardiac tamponade	1	0	1

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Cardiac disorders	Cardiomegaly	3	0	3
	Cardiomyopathy	12	2	1
	Cyanosis	1	0	1
	Extrasystoles	2	0	2
	Mitral valve incompetence	1	0	0
	Myocardial infarction	3	0	1
	Myocarditis	4	2	0
	Palpitations	3	0	0
	Pericardial effusion	3	0	1
	Sinus arrest	1	0	0
	Sinus bradycardia	1	0	0
	Sinus tachycardia	1	0	0
	Supraventricular tachycardia	1	0	0
	Tachycardia	16	0	9
	Torsade de pointes	2	0	1
	Ventricular fibrillation	1	1	1
Ventricular tachycardia	3	0	2	
Congenital, familial and genetic disorders	Cleft lip	1	0	1
	Cleft palate	1	0	0
	Congenital brain damage	1	0	1
	Congenital foot malformation	1	0	0
	Congenital hydrocephalus	1	0	1
	Ebstein's anomaly	1	0	0
	Oesophageal atresia	1	0	1
	Polydactyly	1	0	0
	Renal aplasia	1	0	0
	Tracheo-oesophageal fistula	1	0	1
Ear and labyrinth disorders	Hyperacusis	1	0	1
	Tinnitus	2	0	1
	Vertigo	2	0	1
Endocrine disorders	Cushing's syndrome	2	0	1
	Hyperprolactinaemia	10	0	9
	Inappropriate antidiuretic hormone secretior	1	0	1
Eye disorders	Blepharitis	1	0	1
	Blepharospasm	1	0	1



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Eye disorders	Cataract	2	0	1
	Chromatopsia	1	0	1
	Conjunctivitis	4	0	3
	Eye disorder	1	0	1
	Eye pain	1	0	0
	Miosis	4	0	3
	Mydriasis	1	0	1
	Oculogyration	4	0	3
	Optic neuropathy	1	0	1
	Photophobia	2	0	1
	Vision blurred	5	0	4
	Visual acuity reduced	1	0	1
	Visual disturbance	8	0	6
Gastrointestinal disorders	Abdominal distension	6	0	4
	Abdominal pain	5	0	2
	Ascites	1	0	1
	Colonic pseudo-obstruction	1	0	1
	Constipation	8	0	5
	Diarrhoea	8	0	5
	Dry mouth	8	0	5
	Dyspepsia	2	0	0
	Dysphagia	5	1	3
	Eructation	2	0	1
	Flatulence	6	0	5
	Gastric ulcer	1	0	0
	Gastrointestinal haemorrhage	2	0	2
	Haematemesis	1	0	0
	Ileus	1	0	1
	Mouth ulceration	4	0	3
	Nausea	18	0	10
	Obstruction gastric	1	0	1
	Pancreatitis	6	0	3
	Pancreatitis acute	2	0	1
Rectal haemorrhage	1	0	0	
Salivary gland enlargement	1	0	0	

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Gastrointestinal disorders	Salivary hypersecretion	12	0	4
	Swollen tongue	1	0	0
	Tongue discolouration	1	0	1
	Tongue oedema	5	0	3
	Vomiting	20	0	14
General disorders and administration site conditions	Asthenia	3	0	3
	Chest pain	9	0	5
	Chills	11	0	5
	Condition aggravated	2	0	1
	Death	4	4	1
	Death neonatal	1	0	0
	Discomfort	1	0	1
	Drug effect decreased	1	0	1
	Drug ineffective	16	2	8
	Drug interaction	2	1	0
	Drug withdrawal syndrome	14	1	8
	Drug withdrawal syndrome neonatal	2	0	0
	Face oedema	19	0	17
	Fat necrosis	1	0	0
	Fatigue	13	0	6
	Foaming at mouth	1	0	0
	Gait disturbance	10	1	6
	Generalised oedema	7	0	6
	Gravitational oedema	17	0	16
	Hyperthermia malignant	1	0	0
	Hypothermia	8	0	6
	Influenza like illness	7	0	5
	Malaise	10	0	7
	Oedema	17	0	13
	Oedema peripheral	43	0	39
	Pain	8	0	8
	Paradoxical drug reaction	1	0	1
	Polyserositis	1	0	1
	Pyrexia	56	2	26
	Sluggishness	1	0	1



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General disorders and administration site conditions	Sudden death	9	9	3
	Swelling	1	0	0
	Therapeutic response decreased	2	0	1
	Thirst	5	0	4
Hepatobiliary disorders	Autoimmune hepatitis	1	0	0
	Cholecystitis	1	0	0
	Hepatic function abnormal	53	1	29
	Hepatic steatosis	3	1	1
	Hepatitis	7	0	1
	Hepatitis fulminant	1	0	0
	Hepatocellular damage	2	0	1
	Hepatomegaly	2	0	0
	Hepatosplenomegaly neonatal	1	0	0
	Hyperbilirubinaemia	3	0	1
	Jaundice	7	0	5
	Jaundice cholestatic	1	0	0
	Immune system disorders	Hypersensitivity	2	0
Infections and infestations	Bacteraemia	1	0	1
	Cellulitis	1	0	0
	Eye infection	1	0	1
	Infection	1	0	1
	Pharyngitis	1	0	0
	Pneumonia	7	2	4
	Rash pustular	2	0	1
	Rhinitis	1	0	1
	Sepsis	2	0	1
	Urinary tract infection	1	0	0
	Vaginal infection	1	0	1
Injury, poisoning and procedural complications	Drug exposure during pregnancy	1	0	0
	Drug toxicity	4	3	3
	Fall	2	0	0
	Incorrect dose administered	1	0	1
	Intentional drug misuse	1	0	0
	Intentional overdose	2	0	1
	Overdose	11	3	7



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Injury, poisoning and procedural complicati	Self mutilation	1	0	1
Investigations	Alanine aminotransferase increased	8	0	5
	Ammonia increased	1	0	0
	Antinuclear antibody positive	1	0	1
	Aspartate aminotransferase increased	3	0	2
	Blood alkaline phosphatase increased	6	0	4
	Blood amylase increased	1	0	1
	Blood bilirubin increased	1	0	1
	Blood cholesterol increased	1	0	0
	Blood creatine phosphokinase increased	53	2	27
	Blood glucose fluctuation	1	0	1
	Blood glucose increased	6	0	5
	Blood lactate dehydrogenase increased	2	0	2
	Blood phosphorus decreased	1	0	0
	Blood pressure increased	1	0	0
	Blood prolactin increased	2	0	0
	Blood triglycerides increased	2	0	2
	Body temperature decreased	1	0	0
	Body temperature increased	2	0	0
	Cardiac enzymes increased	1	0	0
	Cardiac murmur	2	0	2
	C-reactive protein increased	3	0	2
	Drug level above therapeutic	2	1	1
	Drug level increased	7	2	2
	Ejection fraction decreased	1	0	0
	Electrocardiogram abnormal	5	0	3
	Electrocardiogram QT prolonged	7	0	7
	Electrocardiogram T wave inversion	1	0	0
	Electroencephalogram abnormal	1	0	1
	Gamma-glutamyltransferase increased	8	0	7
	Heart rate decreased	1	0	1
	Heart rate irregular	1	0	1
	Hepatic enzyme increased	1	0	1
	Immunoglobulins increased	1	0	1
Lipase increased	1	0	0	

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Investigations	Liver function test abnormal	14	0	5
	Lymphocyte count decreased	1	0	0
	Neutrophil count decreased	2	0	2
	Platelet count decreased	1	0	0
	Prothrombin level increased	1	1	0
	Red blood cell sedimentation rate increased	2	0	1
	Troponin increased	3	1	0
	Weight decreased	4	0	2
	Weight increased	87	1	76
	White blood cell count decreased	1	0	0
	White blood cell count increased	1	0	0
	Metabolism and nutrition disorders	Acidosis	1	0
Anorexia		3	0	1
Dehydration		2	0	1
Diabetes mellitus		24	0	22
Diabetes mellitus insulin-dependent		3	0	3
Diabetes mellitus non-insulin-dependent		5	0	5
Diabetic ketoacidosis		3	0	2
Food craving		1	0	1
Glucose tolerance impaired		3	0	2
Hyperammonaemia		1	0	0
Hypercalcaemia		2	1	1
Hyperglycaemia		17	0	14
Hyperkalaemia		2	0	2
Hyperlipidaemia		1	0	0
Hypernatraemia		1	0	0
Hyperproteinaemia		1	0	1
Hypertriglyceridaemia		1	0	1
Hypocalcaemia		1	1	0
Hypoglycaemia neonatal		1	0	0
Hypokalaemia		3	1	1
Hyponatraemia		14	2	8
Hypoproteinaemia		3	0	2
Increased appetite		16	0	15
Ketoacidosis	2	0	2	

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OLANZAPINE		Layer 1 of 1		
Metabolism and nutrition disorders	Obesity	1	0	0
	Polydipsia	8	1	6
Musculoskeletal and connective tissue disorders	Arthralgia	10	0	9
	Arthritis	1	0	1
	Back pain	1	0	1
	Hypertonia neonatal	1	0	0
	Jaw disorder	1	0	1
	Joint stiffness	1	0	0
	Joint swelling	2	0	2
	Mobility decreased	1	0	0
	Muscle rigidity	4	0	2
	Muscle spasms	3	0	3
	Muscle twitching	19	0	15
	Muscular weakness	1	0	0
	Musculoskeletal stiffness	7	0	1
	Myalgia	16	0	11
	Osteoarthritis	4	0	4
	Pain in extremity	1	0	1
Rhabdomyolysis	5	0	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	2	0	2
	Pituitary tumour	1	0	1
	Prolactinoma	1	0	1
Nervous system disorders	Akathisia	23	1	4
	Altered state of consciousness	2	0	1
	Amnesia	6	0	2
	Aphasia	1	0	1
	Asterixis	1	0	0
	Bradykinesia	2	0	0
	Burning sensation	1	0	1
	Carpal tunnel syndrome	1	0	1
	Cerebral haemorrhage neonatal	1	0	0
	Cerebrovascular accident	2	1	2
	Cerebrovascular disorder	1	0	1
	Cholinergic syndrome	1	0	0
	Choreoathetosis	3	0	2



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OLANZAPINE		Layer 1 of 1		
Nervous system disorders	Clonus	1	0	0
	Cognitive disorder	4	0	1
	Cogwheel rigidity	1	0	0
	Coma	8	1	5
	Consciousness fluctuating	4	0	2
	Convulsion	45	2	26
	Convulsion neonatal	1	0	0
	Coordination abnormal	13	1	6
	Cranial nerve disorder	1	0	1
	Dementia	1	0	1
	Depressed level of consciousness	4	0	2
	Diabetic coma	2	0	2
	Disturbance in attention	4	0	2
	Dizziness	19	1	12
	Drooling	1	0	1
	Dysarthria	5	0	5
	Dysgraphia	1	0	1
	Dyskinesia	14	0	12
	Dyspraxia	1	0	1
	Dystonia	22	1	16
	Extrapyramidal disorder	26	0	19
	Facial palsy	1	0	1
	Formication	1	0	1
	Grand mal convulsion	12	0	7
	Haemorrhagic stroke	1	1	1
	Headache	19	0	12
	Hemiparesis	1	0	1
	Hyperkinesia	16	0	11
	Hyperreflexia	5	0	1
	Hypersomnia	1	0	1
	Hypertonia	42	2	19
	Hypoaesthesia	2	0	2
	Hypokinesia	3	0	3
	Incoherent	1	0	0
Loss of consciousness	4	0	2	

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OLANZAPINE		Layer 1 of 1		
Nervous system disorders	Mastication disorder	1	0	0
	Memory impairment	1	0	0
	Muscle contractions involuntary	1	0	1
	Myoclonus	3	0	1
	Neuroleptic malignant syndrome	51	3	20
	Neuropathy	1	0	1
	Neuropathy peripheral	1	0	0
	Nystagmus	1	0	0
	Opisthotonus	3	0	2
	Paraesthesia	4	0	3
	Paralysis	2	0	2
	Paresis	1	0	0
	Parkinsonian gait	1	0	0
	Parkinsonism	4	0	4
	Sedation	6	1	1
	Serotonin syndrome	10	0	1
	Somnolence	46	0	32
	Somnolence neonatal	1	0	1
	Speech disorder	9	0	7
	Syncope	14	0	5
	Tardive dyskinesia	21	1	14
	Transient ischaemic attack	2	0	1
	Tremor	41	1	23
	Tremor neonatal	1	0	0
Unresponsive to stimuli	2	0	1	
Visual field defect	1	0	1	
Pregnancy, puerperium and perinatal conditions	Intra-uterine death	1	0	0
	Jaundice neonatal	1	0	1
	Neonatal disorder	1	0	1
	Oligohydramnios	1	0	0
	Pre-eclampsia	1	0	1
	Weight decrease neonatal	1	0	0
Psychiatric disorders	Abnormal behaviour	1	0	1
	Abnormal sleep-related event	1	0	0
	Affect lability	1	0	1



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OLANZAPINE		Layer 1 of 1		
Psychiatric disorders	Aggression	29	2	9
	Agitation	32	0	14
	Agitation neonatal	1	0	1
	Alcoholism	1	0	1
	Anxiety	12	0	6
	Apathy	3	0	1
	Bruxism	1	0	1
	Catatonia	6	0	3
	Completed suicide	3	3	1
	Confusional state	43	2	23
	Delirium	20	0	9
	Delusion	5	0	3
	Depersonalisation	3	0	3
	Depressed mood	1	0	1
	Depression	11	0	6
	Disorientation	3	0	1
	Drug dependence	1	0	1
	Euphoric mood	3	0	2
	Flat affect	1	0	1
	Hallucination	24	1	13
	Hallucination, auditory	1	0	0
	Hallucination, visual	1	0	1
	Homicidal ideation	10	1	1
	Hypomania	1	0	0
	Insomnia	11	0	8
	Intentional self-injury	3	0	1
	Libido decreased	1	0	1
	Mania	11	0	6
	Nervousness	7	0	2
	Neurosis	8	0	4
	Nightmare	4	0	2
	Obsessive-compulsive disorder	2	0	2
	Orgasmic sensation decreased	1	0	1
	Panic attack	1	0	0
Paranoia	3	0	0	

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OLANZAPINE		Layer 1 of 1		
Psychiatric disorders	Personality disorder	8	0	7
	Psychotic disorder	17	1	10
	Restlessness	6	0	1
	Schizophrenia	1	0	1
	Schizophreniform disorder	2	0	2
	Self injurious behaviour	1	0	0
	Sleep disorder	1	0	1
	Sleep walking	1	0	1
	Social avoidant behaviour	1	0	1
	Stereotypy	1	0	0
	Suicidal behaviour	2	0	0
	Suicidal ideation	29	1	3
	Suicide attempt	36	3	7
	Thinking abnormal	9	1	7
Renal and urinary disorders	Albuminuria	3	0	2
	Anuria	1	0	0
	Enuresis	1	0	0
	Nephritis interstitial	1	0	1
	Nephrotic syndrome	2	0	1
	Nocturia	1	0	1
	Pollakiuria	1	0	1
	Polyuria	9	0	7
	Renal failure	1	0	1
	Renal failure acute	4	1	2
	Renal impairment	4	0	2
	Urinary hesitation	1	0	0
	Urinary incontinence	15	0	9
	Urinary retention	11	0	8
Reproductive system and breast disorders	Amenorrhoea	9	0	8
	Breast enlargement	3	0	2
	Breast mass	2	0	1
	Breast pain	3	0	2
	Ejaculation failure	1	0	1
	Erectile dysfunction	4	0	4
	Galactorrhoea	10	0	10

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Reproductive system and breast disorders	Genital ulceration	1	0	0
	Gynaecomastia	13	0	11
	Menstrual disorder	1	0	1
	Nipple pain	1	0	1
	Ovarian cyst	1	0	1
	Priapism	8	0	7
	Prostatic disorder	1	0	1
	Testicular disorder	1	0	1
	Vaginal haemorrhage	2	0	0
Respiratory, thoracic and mediastinal disorders	Apnoea	2	0	2
	Asthma	1	1	0
	Bronchospasm	5	0	4
	Cough	3	0	2
	Dyspnoea	17	2	10
	Epistaxis	2	0	2
	Hyperventilation	2	0	0
	Hypoxia	2	1	0
	Infantile apnoeic attack	1	0	0
	Nasal polyps	1	0	1
	Pleural effusion	1	0	1
	Pneumonia aspiration	1	0	1
	Productive cough	2	0	2
	Pulmonary embolism	1	1	0
	Pulmonary fibrosis	2	1	1
	Pulmonary hypertension	1	0	0
	Pulmonary oedema	1	0	1
	Respiratory arrest	2	0	0
	Respiratory depression	1	0	1
	Respiratory disorder	1	0	1
Respiratory failure	2	0	2	
Tachypnoea	1	0	0	
Skin and subcutaneous tissue disorders	Acne	8	0	6
	Alopecia	6	0	6
	Angioedema	4	0	2
	Blister	1	0	1

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Skin and subcutaneous tissue disorders	Dermatitis bullous	3	0	3
	Eczema	1	0	1
	Erythema	1	0	1
	Hyperhidrosis	26	1	16
	Leukoplakia	1	0	0
	Nail disorder	1	0	1
	Necrobiosis lipoidica diabetorum	1	0	0
	Pemphigoid	2	0	2
	Periorbital oedema	2	0	2
	Petechiae	1	0	0
	Photosensitivity reaction	9	0	9
	Pruritus	13	0	9
	Psoriasis	2	0	1
	Purpura	6	0	3
	Rash	36	0	22
	Rash erythematous	5	0	5
	Rash generalised	2	1	2
	Rash macular	2	0	1
	Rash maculo-papular	10	0	8
	Rash vesicular	1	0	1
	Skin discolouration	1	0	1
	Skin exfoliation	1	0	1
	Skin odour abnormal	1	0	1
Skin reaction	1	0	0	
Skin striae	1	0	1	
Stevens-Johnson syndrome	3	0	3	
Urticaria	12	0	9	
Surgical and medical procedures	Therapy regimen changed	7	0	4
Vascular disorders	Arterial thrombosis limb	1	0	1
	Blood pressure fluctuation	2	0	0
	Circulatory collapse	4	0	2
	Deep vein thrombosis	3	0	1
	Flushing	2	0	2
	Hot flush	1	0	1
	Hypertension	15	1	11



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Vascular disorders	Hypotension	17	0	11
	Orthostatic hypotension	14	0	10
	Pallor	3	1	1
	Peripheral ischaemia	1	0	0
	Shock	1	1	0
	Vasodilatation	3	0	2