

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MOCLOBEMIDE		Layer 1 of 1		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		738	10	513
<b>- Occurrences of Medicine</b>		748	10	513
<b>- Reactions Related to Medicine</b>		1810	22	1163
Blood and lymphatic system disorders	Anaemia	1	0	0
	Anaemia macrocytic	1	0	1
	Bone marrow failure	1	0	0
	Pancytopenia	3	0	0
	Thrombocytopenia	3	0	2
	Macrocytosis	1	0	1
	Eosinophilia	3	0	0
	Leukopenia	1	0	1
	Agranulocytosis	2	0	1
	Neutropenia	2	0	0
Cardiac disorders	Bradycardia	4	0	1
	Extrasystoles	1	0	0
	Tachycardia	13	0	8
	Atrial fibrillation	1	0	1
	Supraventricular tachycardia	2	0	2
	Ventricular tachycardia	2	0	1
	Palpitations	20	0	14
	Angina pectoris	1	0	1
	Arteriospasm coronary	1	0	0
	Left ventricular failure	1	1	1
	Cardiomyopathy	1	1	1
Congenital, familial and genetic disorders	Talipes	1	0	1
Ear and labyrinth disorders	Deafness	2	0	1
	Hyperacusis	1	0	1
	Tinnitus	13	0	9
	Vertigo	13	0	11
Endocrine disorders	Hyperprolactinaemia	6	0	4
	Inappropriate antidiuretic hormone secretior	4	0	2

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Eye disorders	Conjunctivitis	3	0	2
	Blepharospasm	1	0	0
	Oculogyration	2	0	1
	Mydriasis	5	0	1
	Pupillary reflex impaired	1	0	0
	Photophobia	2	0	2
	Accommodation disorder	1	0	1
	Diplopia	4	0	2
	Vision blurred	1	0	0
	Visual disturbance	18	0	14
	Gastrointestinal disorders	Rectal tenesmus	1	0
Pancreatitis		1	0	1
Rectal haemorrhage		1	0	1
Haematemesis		1	0	1
Melaena		1	0	0
Gastritis		1	0	0
Diarrhoea		50	0	40
Constipation		5	0	5
Flatulence		7	0	6
Abdominal pain		27	0	18
Abdominal pain upper		1	0	1
Dysphagia		5	0	4
Faecal incontinence		1	0	1
Nausea		92	0	64
Vomiting		30	0	17
Duodenal ulcer		1	0	1
Mouth ulceration		1	0	1
Dry mouth		14	0	11
Salivary hypersecretion		4	0	2
Glossitis		2	0	2
Tongue disorder		2	0	2
Glossodynia	1	0	1	
Tongue oedema	4	0	3	
General disorders and administration site conditions	Hypothermia	1	0	0
	Chills	10	0	2



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General disorders and administration site conditions	Pyrexia	14	0	6
	Death	2	2	1
	Sudden death	3	3	0
	Asthenia	14	0	7
	Fatigue	13	0	8
	Malaise	18	0	6
	Gait disturbance	3	0	2
	Chest discomfort	2	0	0
	Influenza like illness	2	0	2
	Thirst	2	0	2
	Face oedema	6	0	6
	Gravitational oedema	6	0	5
	Oedema peripheral	6	0	4
	Pitting oedema	1	0	0
	Chest pain	11	0	7
	Pain	3	0	2
	Drug interaction	2	1	0
	Drug ineffective	17	1	14
	Drug withdrawal syndrome	4	0	3
	Drug withdrawal syndrome neonatal	1	0	0
Therapeutic response decreased	1	0	1	
Therapeutic response increased	1	0	0	
Therapeutic response unexpected	2	0	2	
Hepatobiliary disorders	Hepatitis cholestatic	1	0	1
	Jaundice	2	1	1
	Hepatic function abnormal	15	0	8
	Hepatitis	4	1	1
Immune system disorders	Hypersensitivity	1	0	0
	Anaphylactoid reaction	1	0	1
Infections and infestations	Folliculitis	1	0	0
	Vaginal infection	1	0	1
	Pharyngitis	2	0	2
	Rhinitis	1	0	1
	Herpes simplex	1	0	1
Injury, poisoning and procedural complications	Drug toxicity	2	2	1

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Injury, poisoning and procedural complications	Fall	1	0	0
	Medication error	2	0	0
	Intentional overdose	1	1	0
Investigations	Blood pressure increased	1	0	0
	Blood creatine phosphokinase increased	2	0	1
	Prothrombin level decreased	5	0	0
	Red blood cell sedimentation rate increased	2	0	0
	White blood cell count decreased	1	0	1
	Antinuclear antibody positive	1	0	1
	Weight decreased	1	0	0
	Urine analysis abnormal	2	0	1
	Drug level increased	2	1	0
Metabolism and nutrition disorders	Anorexia	13	0	11
	Increased appetite	2	0	2
	Tetany	2	0	1
	Electrolyte imbalance	1	0	0
	Polydipsia	1	0	1
	Hypokalaemia	2	0	1
	Hyponatraemia	23	0	14
	Dehydration	1	0	1
	Alcohol intolerance	2	0	1
	Glucose tolerance impaired	1	0	1
	Hypoglycaemia	2	0	0
	Gout	1	0	1
Musculoskeletal and connective tissue disorders	Arthritis	3	0	3
	Arthralgia	7	0	6
	Joint swelling	1	0	0
	Osteoarthritis	2	0	2
	Myalgia	13	0	9
	Muscle spasms	3	0	2
	Muscle twitching	6	0	4
	Trismus	1	0	0
	Muscular weakness	1	0	0
	Myopathy	1	0	1
	Rhabdomyolysis	1	0	0



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Musculoskeletal and connective tissue diso	Back pain	3	0	3
Nervous system disorders	Cerebrovascular disorder	3	0	2
	Anosmia	1	0	0
	Encephalopathy	1	0	1
	Hypertensive encephalopathy	2	0	2
	Headache	63	0	53
	Migraine	5	0	3
	Dementia	1	0	0
	Amnesia	8	0	3
	Disturbance in attention	8	0	5
	Chorea	1	0	0
	Choreoathetosis	1	0	1
	Dyskinesia	7	0	2
	Extrapyramidal disorder	5	0	3
	Hyperkinesia	14	0	11
	Tardive dyskinesia	1	0	0
	Dystonia	5	0	1
	Hemiparesis	1	0	1
	Paralysis	1	0	1
	Paresis	1	0	1
	Tremor	33	0	11
	Hyperreflexia	4	0	2
	Coordination abnormal	15	0	10
	Nystagmus	2	0	0
	Coma	2	0	0
	Aphasia	1	0	1
	Consciousness fluctuating	1	0	0
	Lethargy	2	0	1
	Loss of consciousness	1	0	1
	Somnolence	19	0	12
	Stupor	2	0	1
	Syncope	18	0	6
	Clonus	1	0	0
	Dizziness	62	0	41
Myoclonus	1	0	0	

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Nervous system disorders	Hypoaesthesia	10	0	7
	Paraesthesia	24	0	21
	Ageusia	1	0	1
	Dysgeusia	5	0	5
	Neuralgia	2	0	2
	Sensory disturbance	2	0	1
	Dysarthria	6	0	5
	Speech disorder	7	0	4
	Hypertonia	12	0	4
	Hypotonia	1	0	1
	Neuroleptic malignant syndrome	2	0	2
	Serotonin syndrome	29	0	5
	Muscle contractions involuntary	3	0	1
	Neuropathy	1	0	0
	Neuropathy peripheral	2	0	1
	Convulsion	19	0	8
	Convulsions local	1	0	0
Pregnancy, puerperium and perinatal conditions	Intra-uterine death	2	0	2
	Neonatal disorder	1	0	0
Psychiatric disorders	Neurosis	2	0	1
	Obsessive-compulsive disorder	1	0	0
	Agitation	83	1	50
	Anxiety	24	0	16
	Nervousness	7	0	3
	Fear	1	0	1
	Restlessness	1	0	1
	Bruxism	1	0	1
	Confusional state	49	0	27
	Delirium	7	0	3
	Depression	14	0	8
	Decreased interest	1	0	0
	Depersonalisation	11	0	9
	Delusion	4	0	4
	Hallucination	19	0	10
	Thinking abnormal	15	0	11

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Psychiatric disorders	Mania	9	0	8
	Crying	1	0	0
	Euphoric mood	6	0	5
	Apathy	2	0	2
	Aggression	13	0	11
	Paranoia	3	0	3
	Psychotic disorder	6	0	5
	Libido decreased	4	0	3
	Libido increased	2	0	2
	Insomnia	66	0	58
	Nightmare	11	0	11
	Completed suicide	1	1	1
	Suicidal behaviour	1	0	0
	Suicide attempt	6	1	4
Renal and urinary disorders	Oliguria	1	0	1
	Renal failure acute	2	0	0
	Renal impairment	1	0	1
	Dysuria	2	0	1
	Micturition disorder	3	0	3
	Pollakiuria	5	0	5
	Urinary incontinence	2	0	1
	Urinary retention	5	0	3
	Albuminuria	1	0	1
	Haematuria	2	0	1
	Nocturia	3	0	3
Reproductive system and breast disorders	Breast mass	1	0	0
	Gynaecomastia	4	0	3
	Breast pain	3	0	2
	Galactorrhoea	6	0	3
	Suppressed lactation	1	0	0
	Menstrual disorder	4	0	2
	Amenorrhoea	2	0	1
	Ejaculation failure	2	0	2
	Erectile dysfunction	4	0	4
	Sexual dysfunction	2	0	2

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Reproductive system and breast disorders	Testicular pain	1	0	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	2	0	2
	Lung infiltration	1	1	0
	Dyspnoea	16	1	9
	Hyperventilation	1	0	1
	Hypoxia	1	0	0
	Haemoptysis	1	1	0
	Respiratory failure	1	1	0
	Respiratory disorder	1	0	0
	Choking	1	0	1
	Dysphonia	2	0	2
	Epistaxis	1	0	1
	Skin and subcutaneous tissue disorders	Angioedema	2	0
Periorbital oedema		1	0	1
Dermographism		1	0	1
Urticaria		25	0	21
Dermatitis bullous		2	0	2
Erythema multiforme		2	0	1
Dry skin		1	0	1
Skin odour abnormal		1	0	1
Rash erythematous		10	0	9
Skin exfoliation		3	0	3
Photosensitivity reaction		4	0	3
Pruritus		43	0	39
Rash		28	0	18
Rash maculo-papular		9	0	7
Rash morbilliform		2	0	0
Rash vesicular		1	0	1
Lipodystrophy acquired		1	0	0
Acne		2	0	2
Alopecia		6	0	4
Hyperhidrosis		20	0	10
Seborrhoea		1	0	1
Purpura	4	0	3	
Vascular disorders	Peripheral ischaemia	1	0	0





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Vascular disorders	Blood pressure fluctuation	1	0	0
	Circulatory collapse	2	0	1
	Hypotension	11	0	7
	Orthostatic hypotension	10	0	5
	Flushing	17	0	7
	Hot flush	2	0	2
	Pallor	2	0	1
	Hypertension	23	0	12
	Vasculitis	6	0	3