

Medicine summary -moclobemide (to date)

			Case Group	Death Outcomes	Sole	
Case Count			760	13	526	
Reaction Count	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		
Blood and lymphatic system disorders			18	0	6	
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	21	0	15		
	Angina pectoris	1	0	1		
	Arteriospasm coronary	1	0	0		
	Left ventricular failure	1	1	1		
	Cardiomyopathy	1	1	1		
	Cardiac disorders			48	2	31
	Congenital, familial and genetic disorders	Talipes	1	0	1	
		Congenital, familial and genetic disorders			1	0
Ear and labyrinth disorders	Deafness	2	0	1		
	Hyperacusis	2	0	2		
	Tinnitus	13	0	9		
	Vertigo	14	0	11		
	Ear and labyrinth disorders			31	0	23
Endocrine disorders	Hyperprolactinaemia	6	0	4		
	Inappropriate antidiuretic hormone secretion	4	0	2		
	Endocrine disorders			10	0	6
Eye disorders	Periorbital oedema	1	0	1		
	Conjunctivitis	3	0	2		
	Blepharospasm	1	0	0		
	Oculogyric crisis	2	0	1		
	Mydriasis	5	0	1		
	Pupillary reflex impaired	1	0	0		
	Photophobia	2	0	2		
	Accommodation disorder	1	0	1		

Medicine summary -moclobemide (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Eye disorders	Diplopia	4	0	2
		Vision blurred	1	0	0
		Visual impairment	18	0	14
		Eye disorders	39	0	24
	Gastrointestinal disorders	Rectal tenesmus	1	0	1
		Pancreatitis	1	0	1
		Rectal haemorrhage	1	0	1
		Haematemesis	1	0	1
		Melaena	1	0	0
		Gastritis	1	0	0
		Diarrhoea	51	0	41
		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	93	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
		Gastrointestinal disorders	255	0	184
	General disorders and administration site conditions	Hypothermia	1	0	0
		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
Condition aggravated		1	0	1	
Influenza like illness		2	0	2	
Face oedema		6	0	6	
Gravitational oedema		6	0	5	
Oedema		1	0	0	
Oedema peripheral		6	0	4	

Medicine summary - moclobemide (to date)

			Case Group	Death Outcomes	Sole	
Reaction Count	General disorders and administration site conditions	Chest pain	11	0	7	
		Pain	3	0	2	
		Chest discomfort	2	0	0	
		Chills	11	0	3	
		Feeling abnormal	1	0	1	
		Thirst	2	0	2	
		Drug interaction	3	2	1	
		Drug ineffective	19	1	16	
		Therapeutic response decreased	2	0	2	
		Therapeutic response increased	1	0	0	
		Therapeutic response unexpected	2	0	2	
		Therapeutic response unexpected with drug substitution	1	0	1	
		Drug withdrawal syndrome	1	0	0	
		Drug withdrawal syndrome neonatal	1	0	0	
		Product substitution issue	1	0	1	
			General disorders and administration site conditions	151	8	86
		Hepatobiliary disorders	Hepatitis cholestatic	1	0	1
Jaundice	2		1	1		
Hepatic function abnormal	15		0	8		
Hepatitis	4		1	1		
	Hepatobiliary disorders		22	2	11	
Immune system disorders	Hypersensitivity	1	0	0		
	Anaphylactic reaction	2	0	2		
	Anaphylactoid reaction	1	0	1		
		Immune system disorders	4	0	3	
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		
		Infections and infestations	6	0	5	
Injury, poisoning and procedural complications	Drug toxicity	4	4	2		
	Drug exposure during pregnancy	2	0	0		
	Fall	1	0	0		
	Medication error	2	0	0		
	Intentional overdose	1	1	0		
		Injury, poisoning and procedural complications	10	5	2	
Investigations	Blood pressure increased	1	0	0		
	Blood creatine phosphokinase increased	2	0	1		
	Prothrombin level decreased	5	0	0		

Medicine summary -moclobemide (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Investigations	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
		Antidepressant drug level above therapeutic	1	1	1
		Drug level increased	2	1	0
		Amphetamines positive	1	1	1
		Investigations	19	3	6
	Metabolism and nutrition disorders	Decreased appetite	13	0	11
		Increased appetite	2	0	2
		Feeding disorder neonatal	1	0	0
		Tetany	2	0	1
		Electrolyte imbalance	1	0	0
		Polydipsia	1	0	1
		Hypokalaemia	2	0	1
		Hyponatraemia	24	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
		Metabolism and nutrition disorders	53	0	34
	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	7	0	5
		Trismus	1	0	0
		Muscular weakness	1	0	0
		Myopathy	1	0	1
		Rhabdomyolysis	1	0	0
		Back pain	3	0	3
		Musculoskeletal and connective tissue disorders	43	0	31
	Nervous system disorders	Cerebrovascular disorder	3	0	2
		Anosmia	1	0	0
		Encephalopathy	1	0	1
		Hypertensive encephalopathy	2	0	2
		Headache	64	0	54

Medicine summary -moclobemide (to date)

Reaction Count			Case Group	Death Outcomes	Sole
	Nervous system disorders	Migraine	6	0	4
		Dementia	1	0	0
		Amnesia	8	0	3
		Disturbance in attention	9	0	6
		Chorea	1	0	0
		Choreoathetosis	1	0	1
		Dyskinesia	7	0	2
		Extrapyramidal disorder	5	0	3
		Hyperkinesia	13	0	10
		Hypokinesia	1	0	0
		Tardive dyskinesia	1	0	0
		Dystonia	5	0	1
		Hemiparesis	1	0	1
		Paralysis	2	0	2
		Paresis	1	0	1
		Tremor	33	0	11
		Hyperreflexia	4	0	2
		Ataxia	12	0	9
		Balance disorder	1	0	0
		Coordination abnormal	3	0	1
		Nystagmus	2	0	0
		Coma	2	0	0
		Aphasia	2	0	2
		Consciousness fluctuating	1	0	0
		Lethargy	2	0	1
		Loss of consciousness	1	0	1
		Somnolence	20	0	12
		Stupor	2	0	1
		Syncope	18	0	6
		Clonus	1	0	0
		Dizziness	62	0	41
		Myoclonus	1	0	0
		Crying	1	0	0
		Paraesthesia	25	0	22
		Ageusia	1	0	1
		Dysgeusia	5	0	5
		Hypoaesthesia	10	0	7
		Neuralgia	2	0	2
		Sensory disturbance	2	0	1
		Dysarthria	7	0	6
Speech disorder	7	0	4		
Hypertonia	12	0	4		

Medicine summary -moclobemide (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Hypotonia	1	0	1
		Neuroleptic malignant syndrome	2	0	2
		Serotonin syndrome	30	1	5
		Muscle contractions involuntary	3	0	1
		Neuropathy peripheral	3	0	1
		Convulsion	20	0	8
		Convulsions local	1	0	0
		Nervous system disorders	432	1	250
	Pregnancy, puerperium and perinatal conditions	Intra-uterine death	2	0	2
		Foetal growth restriction	1	0	0
		Premature labour	1	0	0
		Pre-eclampsia	1	0	0
		Premature baby	1	0	0
		Neonatal disorder	1	0	0
		Pregnancy, puerperium and perinatal conditions	7	0	2
	Psychiatric disorders	Agitation	80	1	50
		Anxiety	24	0	16
		Nervousness	7	0	3
		Fear	1	0	1
		Neurosis	2	0	1
		Obsessive-compulsive disorder	1	0	0
		Restlessness	1	0	1
		Bruxism	1	0	1
		Confusional state	51	0	28
		Delirium	7	0	3
		Depression	15	0	9
		Decreased interest	1	0	0
		Depersonalisation	11	0	9
		Dissociation	1	0	0
		Delusion	4	0	4
		Hallucination	19	0	10
		Thinking abnormal	15	0	11
		Mania	9	0	8
		Euphoric mood	6	0	5
Apathy		2	0	2	
Aggression		13	0	11	
Paranoia		3	0	3	
Withdrawal syndrome		4	0	3	
Psychotic disorder	6	0	5		
Libido decreased	4	0	3		
Libido increased	2	0	2		

Medicine summary -moclobemide (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Loss of libido	1	0	0
		Insomnia	69	0	59
		Abnormal dreams	1	0	0
		Nightmare	11	0	11
		Completed suicide	2	2	1
		Suicidal behaviour	1	0	0
		Suicide attempt	6	1	4
		Psychiatric disorders	381	4	264
	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
		Renal and urinary disorders	27	0	20
	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
		Testicular pain	1	0	0
		Reproductive system and breast disorders	30	0	19
	Respiratory, thoracic and mediastinal disorders	Bronchospasm	2	0	2
		Lung infiltration	1	1	0
		Pulmonary oedema	1	1	1
		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	

Medicine summary -moclobemide (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Respiratory, thoracic and mediastinal disorders	Dysphonia	2	0	2
		Epistaxis	1	0	1
		Respiratory, thoracic and mediastinal disorders	29	5	17
	Skin and subcutaneous tissue disorders	Angioedema	2	0	1
		Urticaria	25	0	21
		Mechanical urticaria	1	0	1
		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	21	0	11
		Seborrhoea	1	0	1
		Purpura	4	0	3
		Skin and subcutaneous tissue disorders	169	0	129
		Vascular disorders	Peripheral ischaemia	1	0
	Blood pressure fluctuation		1	0	0
	Circulatory collapse		2	0	1
	Hypotension		12	0	8
	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	
Vascular disorders	76		0	39	
Reaction		1861	30	1193	