

moclobemide to end January 2009

			Case Group	Death Outcomes	Sole
Case Count			748	10	520
Medicine	Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0
			Anaemia macrocytic	1	0
			Bone marrow failure	1	0
			Pancytopenia	3	0
			Thrombocytopenia	3	0
			Macrocytosis	1	0
			Eosinophilia	3	0
			Leukopenia	1	0
			Agranulocytosis	2	0
			Neutropenia	2	0
			Blood and lymphatic system disorders	18	0
		Cardiac disorders	Bradycardia	4	0
			Extrasystoles	1	0
			Tachycardia	13	0
			Atrial fibrillation	1	0
			Supraventricular tachycardia	2	0
			Ventricular tachycardia	2	0
			Palpitations	21	0
			Angina pectoris	1	0
			Arteriospasm coronary	1	0
			Left ventricular failure	1	1
			Cardiomyopathy	1	1
			Cardiac disorders	48	2
		Congenital, familial and genetic disorders	Talipes	1	0
			Congenital, familial and genetic disorders	1	0
		Ear and labyrinth disorders	Deafness	2	0
			Hyperacusis	2	0
			Tinnitus	13	0
			Vertigo	14	0
			Ear and labyrinth disorders	31	0
		Endocrine disorders	Hyperprolactinaemia	6	0
			Inappropriate antidiuretic hormone secretion	4	0
			Endocrine disorders	10	0
		Eye disorders	Conjunctivitis	3	0
			Blepharospasm	1	0
			Oculogyric crisis	2	0
			Mydriasis	5	0
			Pupillary reflex impaired	1	0
			Photophobia	2	0
			Accommodation disorder	1	0

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Medicine	Reaction Count			Case Group	Death Outcomes	Sole
Eye disorders		Diplopia	4	0	2	
		Vision blurred	1	0	0	
		Visual impairment	18	0	14	
		Eye disorders	38	0	23	
		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	
Gastrointestinal disorders		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	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	254	0	183	
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	
		Influenza like illness	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	

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Medicine	Reaction Count	General disorders and administration site conditions	Case Group	Death Outcomes	Sole	
				3	0	
				0	2	
				2	0	
				10	0	
				1	0	
				2	0	
				2	1	
				18	1	
				2	2	
				1	0	
				2	0	
				1	1	
				146	7	
				81		
			Hepatobiliary disorders	Hepatitis cholestatic	1	
				Jaundice	0	
				Hepatic function abnormal	1	
				Hepatitis	8	
				Hepatobiliary disorders	1	
			Immune system disorders	Hypersensitivity	22	
				Anaphylactoid reaction	2	
				Immune system disorders	11	
			Infections and infestations	Folliculitis	0	
				Vaginal infection	1	
				Pharyngitis	0	
				Rhinitis	2	
				Herpes simplex	1	
				Infections and infestations	1	
			Injury, poisoning and procedural complications	Drug toxicity	6	
				Fall	0	
				Medication error	2	
				Intentional overdose	0	
				Injury, poisoning and procedural complications	1	
			Investigations	Blood pressure increased	3	
				Blood creatine phosphokinase increased	1	
				Prothrombin level decreased	0	
				Red blood cell sedimentation rate increased	0	
				White blood cell count decreased	0	
				Antinuclear antibody positive	1	

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole
		Weight decreased	1	0	0
		Urine analysis abnormal	2	0	1
		Drug level increased	2	1	0
		Investigations	17	1	4
		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
		Metabolism and nutrition disorders	51	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
		Migraine	5	0	3
		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

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Medicine	Reaction Count	Nervous system disorders		Case Group	Death Outcomes	Sole
		Extrapyramidal disorder	5	0	3	
		Hyperkinesia	14	0	11	
		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	21	0	13	
		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	
		Hypoesthesia	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	
		Hypotonia	1	0	1	
		Neuroleptic malignant syndrome	2	0	2	
		Serotonin syndrome	29	0	5	
		Muscle contractions involuntary	3	0	1	
		Neuropathy peripheral	3	0	1	
		Convulsion	19	0	8	
		Convulsions local	1	0	0	

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Medicine	Reaction Count			Case Group	Death Outcomes	Sole
		Nervous system disorders	Nervous system disorders	431	0	251
		Pregnancy, puerperium and perinatal conditions	Intra-uterine death	2	0	2
			Ectopic pregnancy	1	0	0
			Neonatal disorder	1	0	0
			Pregnancy, puerperium and perinatal conditions	4	0	2
		Psychiatric disorders	Agitation	84	1	51
			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	50	0	28
			Delirium	7	0	3
			Depression	14	0	8
			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
			Loss of libido	1	0	0
			Insomnia	69	0	59
			Abnormal dreams	1	0	0
			Nightmare	11	0	11
			Completed suicide	1	1	1
			Suicidal behaviour	1	0	0
			Suicide attempt	6	1	4
			Psychiatric disorders	382	3	264
		Renal and urinary disorders	Oliguria	1	0	1
			Renal failure acute	2	0	0
			Renal impairment	1	0	1

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Medicine	Reaction Count				Case Group	Death Outcomes	Sole
				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
				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
				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
				Respiratory, thoracic and mediastinal disorders	28	4	16
				Skin and subcutaneous tissue disorders	Angioedema	2	0
				Periorbital oedema	1	0	1
				Urticaria	25	0	21
				Mechanical urticaria	1	0	1
				Dermatitis bullous	2	0	2

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Medicine	Reaction Count			Case Group	Death Outcomes	Sole
Skin and subcutaneous tissue disorders			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	170	0	130
Vascular disorders			Peripheral ischaemia	1	0	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				1841	22	1182