

Medicine summary -mianserin (to end January 2009)

			Case Group	Death Outcomes	Sole	
Case Count			441	12	271	
Reaction Count	Blood and lymphatic system disorders	Anaemia	8	0	4	
		Bone marrow failure	4	0	2	
		Pancytopenia	4	1	1	
		Thrombocytopenia	13	0	7	
		Lymphadenopathy	2	0	1	
		Splenomegaly	1	0	1	
		Eosinophilia	2	0	1	
		Leukocytosis	1	0	0	
		Lymphocytosis	1	0	1	
		Leukopenia	13	1	9	
		Lymphopenia	3	0	2	
		Agranulocytosis	42	3	22	
		Neutropenia	51	2	32	
		Blood and lymphatic system disorders			145	7
	Cardiac disorders	Bradycardia	8	0	5	
		Extrasystoles	2	0	0	
		Tachycardia	5	0	1	
		Atrial fibrillation	2	0	2	
		Cardiac arrest	1	0	1	
		Palpitations	5	0	2	
		Coronary artery disease	1	1	0	
		Angina pectoris	1	0	0	
		Myocardial infarction	2	1	1	
		Cardiac failure	1	1	1	
		Left ventricular failure	1	0	1	
Pericarditis		1	0	0		
Cardiac disorders			30	3	14	
Congenital, familial and genetic disorders		Gastrointestinal malformation	1	0	0	
	Congenital, familial and genetic disorders			1	0	0
Ear and labyrinth disorders	Deafness	1	0	0		
	Tinnitus	2	0	1		
	Vertigo	1	0	1		
	Ear and labyrinth disorders			4	0	2
Endocrine disorders	Hypothyroidism	2	0	0		
	Endocrine disorders			2	0	0
Eye disorders	Lacrimal disorder	2	0	2		
	Conjunctivitis	2	0	1		
	Diplopia	3	0	2		
	Vision blurred	1	0	0		
	Visual impairment	6	0	2		
	Eye disorders			14	0	7

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Reaction Count	Gastrointestinal disorders	Gingivitis	2	0	2	
		Gingival bleeding	1	0	0	
		Gastrointestinal haemorrhage	1	1	0	
		Haematemesis	1	1	0	
		Melaena	1	1	0	
		Diarrhoea	7	0	4	
		Constipation	2	0	1	
		Flatulence	2	0	1	
		Abdominal pain	3	0	2	
		Abdominal pain upper	1	0	1	
		Dysphagia	3	0	2	
		Faecal incontinence	1	0	0	
		Nausea	17	0	11	
		Vomiting	3	0	1	
		Mouth ulceration	4	0	4	
		Stomatitis	1	0	1	
		Dry mouth	1	0	1	
		Tongue oedema	1	0	1	
			Gastrointestinal disorders	52	3	32
		General disorders and administration site conditions	Pyrexia	33	0	19
Sudden death	3		3	0		
Asthenia	4		0	4		
Fatigue	15		0	7		
Malaise	11		0	8		
Gait disturbance	4		0	2		
Influenza like illness	1		0	1		
Face oedema	3		0	2		
Gravitational oedema	3		0	3		
Oedema	3		0	3		
Oedema peripheral	8		0	8		
Chest pain	1		0	1		
Pain	3		0	2		
Chills	7		0	5		
Drug ineffective	2		0	1		
	General disorders and administration site conditions		101	3	66	
Hepatobiliary disorders	Hepatitis cholestatic		2	0	1	
	Jaundice	13	0	9		
	Hepatic function abnormal	38	0	19		
	Hepatic steatosis	1	0	1		
	Hepatitis	4	0	3		
	Hepatocellular injury	3	0	1		

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Reaction Count	Hepatobiliary disorders	Hepatobiliary disorders	61	0	34	
	Infections and infestations	Cellulitis	1	0	1	
		Candidiasis	1	0	0	
		Abscess	1	0	1	
		Infection	3	0	2	
		Pneumonia	3	0	2	
		Sepsis	9	1	5	
		Furuncle	1	0	1	
		Pharyngitis	8	0	2	
		Rhinitis	2	0	2	
		Lymphangitis	1	0	1	
			Infections and infestations	30	1	17
		Injury, poisoning and procedural complications	Therapeutic agent toxicity	1	0	0
	Overdose		1	0	1	
			Injury, poisoning and procedural complications	2	0	1
	Investigations	Electrocardiogram abnormal	2	0	0	
		Prothrombin level decreased	1	0	1	
		Red blood cell sedimentation rate increased	3	0	1	
		Liver function test abnormal	1	0	1	
		Transaminases increased	1	0	1	
		Weight decreased	3	0	2	
		Weight increased	3	0	3	
			Investigations	14	0	9
	Metabolism and nutrition disorders	Decreased appetite	8	0	5	
		Increased appetite	1	0	1	
		Hypocalcaemia	1	0	0	
		Polydipsia	1	0	0	
		Hyponatraemia	5	0	1	
		Dehydration	2	0	0	
		Hyperglycaemia	4	0	3	
		Hypercholesterolaemia	2	0	2	
			Metabolism and nutrition disorders	24	0	12
	Musculoskeletal and connective tissue disorders	Arthritis	10	0	8	
		Arthropathy	1	0	1	
		Arthralgia	34	0	31	
		Joint swelling	1	0	1	
		Osteoarthritis	2	0	2	
		Myalgia	18	0	13	
		Muscle spasms	2	0	2	
		Back pain	3	0	1	
		Tenosynovitis	1	0	1	

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			Case Group	Death Outcomes	Sole
Reaction Count	Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	72	0	60
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	1	0	0
		Brain neoplasm benign	1	0	1
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0	1
	Nervous system disorders	Encephalopathy	1	0	1
		Headache	13	0	10
		Dementia	1	0	0
		Choreoathetosis	1	0	1
		Dyskinesia	1	0	1
		Extrapyramidal disorder	2	0	2
		Hyperkinesia	5	0	5
		Hypokinesia	1	0	0
		Psychomotor hyperactivity	1	0	0
		Tardive dyskinesia	1	0	1
		Dystonia	1	0	1
		Paresis	1	0	1
		Tremor	5	0	2
		Ataxia	5	0	1
		Coordination abnormal	2	0	1
		Nystagmus	1	0	0
		Somnolence	18	0	16
		Syncope	13	0	7
		Dizziness	12	0	10
		Paraesthesia	9	0	4
		Dysgeusia	2	0	2
		Hypoaesthesia	2	0	0
		Restless legs syndrome	1	0	1
		Speech disorder	3	0	0
		Hypertonia	4	0	1
		Neuroleptic malignant syndrome	1	0	0
		Serotonin syndrome	1	0	0
		Muscle contractions involuntary	1	0	0
		Neuropathy peripheral	2	0	0
Grand mal convulsion		3	0	2	
Convulsion	6	0	3		
Epilepsy	1	0	0		
	Nervous system disorders	121	0	73	
Pregnancy, puerperium and perinatal conditions	Neonatal disorder	1	0	1	
	Pregnancy, puerperium and perinatal conditions	1	0	1	
Psychiatric disorders	Agitation	10	1	3	

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Reaction Count	Psychiatric disorders	Anxiety	3	0	3	
		Nervousness	1	0	1	
		Panic attack	1	0	0	
		Neurosis	2	0	2	
		Confusional state	16	1	8	
		Delirium	2	0	0	
		Depression	2	0	1	
		Depersonalisation	1	0	1	
		Hallucination	6	0	3	
		Aggression	1	0	0	
		Paranoia	2	0	1	
		Withdrawal syndrome	1	0	0	
		Libido decreased	2	0	1	
		Insomnia	8	0	6	
		Nightmare	15	0	12	
		Sleep disorder	5	0	5	
		Suicidal ideation	1	0	1	
		Suicide attempt	1	0	1	
			Psychiatric disorders	80	2	49
		Renal and urinary disorders	Renal impairment	5	0	1
Urinary incontinence	2		0	1		
Urinary retention	3		0	2		
Albuminuria	2		0	1		
Polyuria	1		0	0		
	Renal and urinary disorders		13	0	5	
Reproductive system and breast disorders	Menstrual disorder	1	0	1		
	Erectile dysfunction	1	0	0		
		Reproductive system and breast disorders	2	0	1	
Respiratory, thoracic and mediastinal disorders	Bronchospasm	2	0	2		
	Alveolitis allergic	1	0	1		
	Eosinophilic pneumonia	1	0	0		
	Pulmonary fibrosis	1	0	1		
	Pleural effusion	1	0	1		
	Pulmonary embolism	2	2	0		
	Apnoea	1	0	1		
	Dyspnoea	2	0	0		
	Hyperventilation	1	0	0		
	Cough	1	0	0		
	Dysphonia	1	0	1		
	Epistaxis	1	0	0		
		Respiratory, thoracic and mediastinal disorders	15	2	7	
Skin and subcutaneous tissue disorders	Angioedema	1	0	1		

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Reaction Count	Skin and subcutaneous tissue disorders	Periorbital oedema	3	0	2	
		Urticaria	3	0	3	
		Dermatitis bullous	1	0	1	
		Skin necrosis	1	0	1	
		Skin reaction	1	0	0	
		Dermatitis	1	0	1	
		Eczema	1	0	1	
		Rash erythematous	2	0	2	
		Skin exfoliation	1	0	0	
		Photosensitivity reaction	3	0	3	
		Pruritus	19	0	8	
		Rash	18	0	10	
		Rash maculo-papular	14	0	6	
		Rash vesicular	1	0	0	
		Alopecia	2	0	1	
		Hyperhidrosis	9	0	6	
		Hair colour changes	1	0	0	
		Purpura	6	1	2	
			Skin and subcutaneous tissue disorders	88	1	48
		Reaction Count	Vascular disorders	Hypotension	9	0
Orthostatic hypotension	8			0	2	
Angiopathy	1			0	0	
Flushing	1			0	0	
Pallor	1			0	1	
Haematoma	1			0	1	
Hypertension	3			0	2	
Phlebitis	1			0	1	
	Vascular disorders			25	0	13
	Reaction	899	22	535		