

Medicine summary -mianserin (to date)

			Case Group	Death Outcomes	Sole	
Case Count			443	12	272	
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	83
			Cardiac disorders	Bradycardia	8	0
		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
			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
			Periorbital oedema	3	0	2
			Conjunctivitis	2	0	1
			Diplopia	3	0	2
			Vision blurred	1	0	0
			Visual impairment	6	0	2

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Reaction Count	Eye disorders	Eye disorders	17	0	9	
	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		

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Reaction Count	Hepatobiliary disorders	Hepatocellular injury	3	0	1
		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
	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	6	0	1
		Dehydration	2	0	0
		Hyperglycaemia	4	0	3
		Hypercholesterolaemia	2	0	2
		Metabolism and nutrition disorders	25	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
		Loss of consciousness	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	7	0	4		
Epilepsy	1	0	0		
	Nervous system disorders	123	0	74	
Pregnancy, puerperium and perinatal conditions	Neonatal disorder	1	0	1	
	Pregnancy, puerperium and perinatal conditions	1	0	1	

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			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Agitation	10	1	3
		Anxiety	3	0	3
		Nervousness	1	0	1
		Panic attack	1	0	0
		Neurosis	2	0	2
		Confusional state	17	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	81	2
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

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			Case Group	Death Outcomes	Sole
Reaction Count	Skin and subcutaneous tissue disorders	Angioedema	1	0	1
		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		85	1
	Vascular disorders	Hypotension	9	0	6
		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			903	22	536