

nortriptyline hydrochloride to end January 2009

				Case Group	Death Outcomes	Sole
Case Count				118	2	57
Medicine	Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	0
			Pancytopenia	1	1	1
			Haemolytic anaemia	1	0	0
			Coombs positive haemolytic anaemia	1	0	0
			Thrombocytopenia	2	1	1
			Leukocytosis	1	0	0
			Neutropenia	4	0	0
			Blood and lymphatic system disorders	11	2	2
		Cardiac disorders	Atrioventricular block	1	0	0
			Tachycardia	4	0	3
			Atrial fibrillation	1	0	0
			Supraventricular tachycardia	1	0	1
			Palpitations	1	0	1
			Cardiac disorders	8	0	5
		Congenital, familial and genetic disorders	Multiple congenital abnormalities	2	0	0
			Anal atresia	1	0	0
			Oesophageal atresia	1	0	0
			Syndactyly	1	0	0
			Talipes	1	0	0
			Congenital musculoskeletal anomaly	1	0	0
			Congenital, familial and genetic disorders	7	0	0
		Ear and labyrinth disorders	Tinnitus	4	0	2
			Vertigo	3	0	2
			Ear and labyrinth disorders	7	0	4
		Eye disorders	Visual impairment	4	0	0
			Scotoma	1	0	0
			Eye disorders	5	0	0
		Gastrointestinal disorders	Anal pruritus	1	0	1
			Gingival hyperplasia	1	0	0
			Gingival bleeding	1	0	1
			Diarrhoea	1	0	1
			Constipation	1	0	1
			Ileus paralytic	1	0	0
			Abdominal pain	3	0	2
			Breath odour	1	0	1
			Dysphagia	1	0	1
			Nausea	5	0	1
			Vomiting	6	0	4
			Lip swelling	1	0	0
			Mouth ulceration	2	0	1
			Stomatitis	1	0	0

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Gastrointestinal disorders	Dry mouth	8	0	6
			Tongue oedema	1	0	0
			Gastrointestinal disorders	35	0	20
		General disorders and administration site conditions	Hyperpyrexia	1	1	1
			Pyrexia	2	0	0
			Sudden death	1	1	1
			Asthenia	1	0	0
			Fatigue	1	0	0
			Malaise	2	0	0
			Face oedema	1	0	1
			Generalised oedema	1	0	1
			Chills	1	0	0
			General disorders and administration site conditions	11	2	4
			Hepatobiliary disorders	Jaundice	2	0
		Hepatic function abnormal		4	0	1
		Hepatobiliary disorders		6	0	2
		Infections and infestations	Vaginal infection	1	0	0
			Pharyngitis	1	0	1
			Infections and infestations	2	0	1
		Investigations	Weight increased	2	0	1
			Urine analysis abnormal	1	0	1
			Drug level increased	3	0	0
			Investigations	6	0	2
		Metabolism and nutrition disorders	Anorexia	2	0	0
			Metabolism and nutrition disorders	2	0	0
		Musculoskeletal and connective tissue disorders	Muscle twitching	2	0	1
			Musculoskeletal and connective tissue disorders	2	0	1
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute leukaemia	2	0	0
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0	0
		Nervous system disorders	Encephalopathy	1	0	0
			Headache	2	0	0
			Akathisia	1	0	0
			Dyskinesia	2	0	0
			Extrapyramidal disorder	1	0	0
			Dystonia	1	0	0
			Paresis	2	0	2
			Tremor	6	0	6
			Ataxia	2	0	0
			Somnolence	4	0	3
			Syncope	5	0	3
		Dizziness	9	0	7	

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Nervous system disorders	Paraesthesia	1	0	1
			Dysgeusia	2	0	1
			Speech disorder	1	0	1
			Serotonin syndrome	2	0	0
			Grand mal convulsion	4	0	3
			Convulsion	4	0	3
			Nervous system disorders	50	0	30
		Pregnancy, puerperium and perinatal conditions	Premature baby	1	0	0
			Pregnancy, puerperium and perinatal conditions	1	0	0
		Psychiatric disorders	Agitation	5	0	1
			Anxiety	4	0	0
			Nervousness	1	0	1
			Neurosis	2	0	0
			Attention deficit/hyperactivity disorder	1	0	1
			Confusional state	9	0	6
			Disorientation	1	0	1
			Delirium	2	0	1
			Depersonalisation	1	0	0
			Hallucination	5	0	1
			Affect lability	1	0	1
			Paranoia	2	0	0
			Insomnia	1	0	1
			Nightmare	3	0	3
			Suicide attempt	1	0	0
			Psychiatric disorders	39	0	17
			Renal and urinary disorders	Renal impairment	2	0
		Urinary retention		3	0	2
		Haematuria		1	1	1
		Renal and urinary disorders		6	1	3
		Reproductive system and breast disorders	Gynaecomastia	1	0	0
			Ejaculation failure	1	0	1
			Reproductive system and breast disorders	2	0	1
		Respiratory, thoracic and mediastinal disorders	Infantile apnoeic attack	1	0	0
			Dyspnoea	1	0	1
			Hyperventilation	1	0	0
			Cough	2	0	0
			Dysphonia	1	0	1
			Respiratory, thoracic and mediastinal disorders	6	0	2
		Skin and subcutaneous tissue disorders	Periorbital oedema	1	0	0
			Dermatitis bullous	2	0	0
			Rash erythematous	1	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
	Skin and subcutaneous tissue disorders	Photosensitivity reaction	3	0	1	
		Pruritus	4	0	2	
		Rash	3	1	3	
		Rash maculo-papular	2	0	2	
		Hyperhidrosis	1	0	1	
		Nail disorder	1	0	1	
		Purpura	3	2	2	
		Skin and subcutaneous tissue disorders	21	3	13	
	Surgical and medical procedures	Therapy regimen changed	1	0	1	
		Surgical and medical procedures	1	0	1	
	Vascular disorders	Peripheral ischaemia	1	0	0	
		Shock	1	0	1	
		Hypotension	5	0	3	
		Orthostatic hypotension	3	0	1	
		Flushing	1	0	1	
		Hot flush	1	0	0	
		Hypertension	1	0	0	
		Vascular disorders	13	0	6	
	Reaction			243	8	114