

Medicine summary -dothiepin (to date)

			Case Group	Death Outcomes	Sole	
Case Count			450	17	230	
Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	0	
		Aplastic anaemia	1	0	0	
		Bone marrow failure	2	0	1	
		Pancytopenia	3	1	1	
		Thrombocytopenia	7	0	2	
		Red blood cell abnormality	1	0	1	
		Lymphadenopathy	1	0	1	
		Eosinophilia	2	0	0	
		Leukocytosis	1	0	0	
		Leukopenia	5	0	1	
		Agranulocytosis	4	1	1	
		Neutropenia	1	0	1	
		Blood and lymphatic system disorders		29	2	9
		Cardiac disorders	Arrhythmia	2	0	1
	Bradycardia		1	0	0	
	Extrasystoles		2	0	1	
	Tachycardia		9	1	3	
	Atrial fibrillation		1	0	1	
	Cardiac arrest		2	1	1	
	Torsade de pointes		2	0	0	
	Ventricular fibrillation		1	0	1	
	Ventricular tachycardia		1	0	0	
	Cyanosis		1	0	0	
	Palpitations		9	0	6	
	Aortic valve incompetence		1	0	0	
	Acute myocardial infarction		1	0	0	
	Angina pectoris		2	0	1	
	Arteriospasm coronary		1	0	0	
	Myocardial infarction		1	1	0	
	Cardiogenic shock		1	0	0	
	Right ventricular failure		1	0	1	
	Cardiomyopathy		1	0	1	
	Cardiac disorders		40	3	17	
	Congenital, familial and genetic disorders		Heart disease congenital	1	0	1
		Multiple congenital abnormalities	1	0	1	
		Congenital foot malformation	1	0	1	
		Limb reduction defect	1	0	1	
		Congenital, familial and genetic disorders		4	0	4
	Ear and labyrinth disorders	Deafness	1	0	1	
		Hyperacusis	1	0	1	
		Tinnitus	4	0	4	

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Reaction Count	Ear and labyrinth disorders	Vertigo	2	0	2	
		Ear and labyrinth disorders	8	0	8	
	Endocrine disorders	Inappropriate antidiuretic hormone secretion	2	0	1	
		Hypothyroidism	1	0	0	
		Endocrine disorders	3	0	1	
	Eye disorders	Xerophthalmia	1	0	1	
		Dry eye	1	0	1	
		Lacrimal disorder	1	0	0	
		Periorbital oedema	1	0	0	
		Glaucoma	1	0	1	
		Conjunctivitis	2	0	2	
		Mydriasis	1	0	0	
		Photophobia	1	0	1	
		Retinal haemorrhage	1	0	0	
		Accommodation disorder	2	0	1	
		Diplopia	1	0	1	
		Vision blurred	3	0	1	
		Visual impairment	12	0	9	
		Eye disorders	28	0	18	
		Gastrointestinal disorders	Gingivitis	1	0	1
			Haematemesis	2	0	0
	Melaena		1	0	0	
	Enteritis		1	0	0	
	Diarrhoea		4	0	4	
	Constipation		7	0	5	
	Dyspepsia		5	0	2	
	Abdominal distension		1	0	0	
	Flatulence		1	0	1	
	Abdominal pain		12	0	8	
	Nausea		19	0	12	
	Vomiting		8	0	5	
	Duodenal ulcer haemorrhage		1	1	0	
	Duodenal ulcer perforation		1	0	0	
	Gastric ulcer perforation		1	0	0	
	Peptic ulcer perforation		1	1	0	
	Mouth ulceration		1	0	1	
	Stomatitis		1	0	1	
	Retroperitoneal fibrosis		1	0	0	
	Dry mouth		12	0	6	
	Saliva altered		1	0	1	
	Salivary gland enlargement		2	0	1	
	Glossitis	1	0	1		

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Reaction Count	Gastrointestinal disorders	Swollen tongue	1	0	1
		Tongue discolouration	1	0	0
		Tongue oedema	2	0	1
		Gastrointestinal disorders	89	2	51
	General disorders and administration site conditions	Pyrexia	18	1	9
		Sudden death	2	2	0
		Asthenia	4	0	2
		Fatigue	13	0	5
		Malaise	6	0	4
		Gait disturbance	4	0	0
		Condition aggravated	1	0	1
		Influenza like illness	1	0	0
		Enanthema	1	0	0
		Face oedema	2	0	2
		Gravitational oedema	2	0	0
		Oedema	1	0	1
		Oedema peripheral	3	0	2
		Chest pain	7	0	1
		Pain	2	0	1
		Chills	3	0	1
		Thirst	1	0	0
		Drug interaction	1	1	0
		Adverse drug reaction	1	0	1
		Drug ineffective	10	0	7
		Drug tolerance	1	0	1
		Therapeutic response decreased	1	0	0
		Therapeutic response unexpected with drug substitution	2	0	2
		Drug withdrawal syndrome neonatal	1	0	0
		General disorders and administration site conditions	88	4	40
	Hepatobiliary disorders	Hepatitis cholestatic	3	0	2
		Jaundice	11	1	1
		Hepatic function abnormal	20	1	9
		Hepatic failure	1	0	0
		Hepatic cirrhosis	1	0	0
		Hepatosplenomegaly	1	1	0
		Hepatic steatosis	1	0	1
Hepatitis		8	0	1	
Hepatocellular injury		2	0	0	
Hepatobiliary disorders	48	3	14		
Immune system disorders	Hypersensitivity	1	0	0	

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Reaction Count	Immune system disorders	Anaphylactic reaction	1	0	1
		Immune system disorders	2	0	1
	Infections and infestations	Bacterial infection	1	0	0
		Meningitis	1	1	0
		Abscess of salivary gland	1	0	1
		Pneumonia	2	1	0
		Laryngitis	1	0	1
		Pharyngitis	5	0	4
		Cystitis	1	0	0
		Infections and infestations	12	2	6
		Injury, poisoning and procedural complications	Drug exposure during pregnancy	4	0
	Fall		3	0	0
	Sunburn		1	0	1
	Intentional overdose		1	0	1
	Overdose		2	2	1
	Injury, poisoning and procedural complications		11	2	5
	Investigations	Electrocardiogram QT prolonged	1	0	1
		Electrocardiogram abnormal	3	0	0
		Blood creatine phosphokinase increased	1	0	0
		Red blood cell sedimentation rate increased	2	0	1
		Neutrophil count increased	1	0	0
		White blood cell count increased	1	0	0
		Gamma-glutamyltransferase increased	1	0	0
		Antinuclear antibody positive	1	0	1
		Immunoglobulins decreased	1	0	0
		Blood folate abnormal	1	0	0
		Electroencephalogram abnormal	1	0	0
		Weight decreased	3	0	2
		Weight increased	1	0	1
		Drug level increased	1	0	0
		Investigations	19	0	6
	Metabolism and nutrition disorders	Decreased appetite	8	0	5
		Increased appetite	1	0	1
		Feeding disorder neonatal	1	0	0
		Hypercalcaemia	1	0	0
		Hypochloraemia	2	0	0
		Polydipsia	1	0	1
		Hypokalaemia	3	1	0
		Hyponatraemia	10	0	3
		Hyperglycaemia	1	0	1
		Metabolism and nutrition disorders	28	1	11

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			Case Group	Death Outcomes	Sole
Reaction Count	Musculoskeletal and connective tissue disorders	Lupus-like syndrome	1	0	1
		Arthritis	1	0	1
		Arthralgia	3	0	1
		Myalgia	4	0	1
		Muscle spasms	7	0	3
		Muscle twitching	6	0	4
		Myopathy	2	0	1
		Rhabdomyolysis	1	0	0
		Musculoskeletal stiffness	1	0	1
		Sensation of heaviness	1	0	1
		Back pain	1	0	1
		Musculoskeletal and connective tissue disorders	28	0	15
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	2	1
Bronchioloalveolar carcinoma	1		1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3		2	0	
Nervous system disorders	Cerebral haemorrhage	1	0	0	
	Transient ischaemic attack	2	0	0	
	VIIth nerve paralysis	1	0	1	
	Parosmia	2	0	1	
	Encephalopathy	2	0	1	
	Headache	19	0	11	
	Migraine	4	0	2	
	Amnesia	7	0	3	
	Cognitive disorder	1	0	0	
	Disturbance in attention	4	0	1	
	Mental impairment	1	0	1	
	Dyskinesia	3	0	2	
	Extrapyramidal disorder	2	0	0	
	Hyperkinesia	3	0	3	
	Tardive dyskinesia	2	0	0	
	Dystonia	3	0	1	
	Quadriplegia	1	0	0	
	Parkinson's disease	1	0	1	
	Tremor	21	0	10	
	Hyperreflexia	3	0	0	
	Ataxia	9	0	4	
	Balance disorder	1	0	1	
	Cerebellar syndrome	2	0	1	
	Coordination abnormal	2	0	0	
	Coma	2	0	1	

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Reaction Count	Nervous system disorders	Aphasia	1	0	0	
		Consciousness fluctuating	1	0	0	
		Depressed level of consciousness	1	0	0	
		Lethargy	2	0	1	
		Loss of consciousness	2	0	1	
		Somnolence	6	0	3	
		Syncope	5	0	3	
		Dizziness	20	0	9	
		Hyperaesthesia	1	0	1	
		Paraesthesia	20	0	12	
		Dysgeusia	2	0	2	
		Hypoaesthesia	2	0	2	
		Restless legs syndrome	1	0	1	
		Sensory disturbance	1	0	1	
		Dysarthria	1	0	0	
		Speech disorder	1	0	0	
		Anticholinergic syndrome	1	0	1	
		Hypertonia	5	0	1	
		Neuroleptic malignant syndrome	3	0	0	
		Serotonin syndrome	5	1	0	
		Muscle contractions involuntary	1	0	1	
		Neuropathy peripheral	2	0	2	
		Grand mal convulsion	6	0	4	
		Convulsion	18	0	5	
			Nervous system disorders	207	1	95
		Pregnancy, puerperium and perinatal conditions	Intra-uterine death	2	1	1
			Foetal cardiac disorder	1	0	1
Foetal growth restriction	1		1	0		
Small for dates baby	1		0	0		
Pregnancy, puerperium and perinatal conditions	5		2	2		
Psychiatric disorders	Agitation	21	1	15		
	Anxiety	9	0	3		
	Nervousness	2	0	2		
	Neurosis	1	0	0		
	Catatonia	2	0	1		
	Restlessness	2	0	2		
	Bruxism	1	0	0		
	Communication disorder	1	0	1		
	Confusional state	24	2	8		
	Disorientation	1	0	1		
	Delirium	5	0	4		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Psychiatric disorders	Depression	6	0	4	
		Depersonalisation	3	0	1	
		Delusion	1	0	0	
		Hallucination	15	1	8	
		Morbid thoughts	1	0	0	
		Thinking abnormal	4	0	1	
		Mania	2	0	1	
		Affect lability	3	0	3	
		Anger	2	0	2	
		Emotional disorder	1	0	0	
		Mood swings	1	0	0	
		Aggression	4	0	2	
		Homicidal ideation	1	0	1	
		Paranoia	6	1	2	
		Withdrawal syndrome	5	0	5	
		Psychotic disorder	2	0	0	
		Libido decreased	2	0	1	
		Loss of libido	2	0	0	
		Insomnia	17	0	12	
		Nightmare	11	0	6	
		Completed suicide	1	1	1	
		Suicidal ideation	4	0	3	
		Suicide attempt	2	0	1	
		Psychiatric disorders		165	6	91
		Renal and urinary disorders	Oliguria	1	1	0
			Renal failure acute	3	1	0
			Renal impairment	2	0	0
			Dysuria	3	0	3
			Micturition disorder	1	0	1
			Pollakiuria	1	0	1
			Urinary incontinence	1	0	0
			Urinary retention	6	0	2
			Chromaturia	1	0	0
			Polyuria	2	0	2
			Renal and urinary disorders	21	2	9
	Reproductive system and breast disorders	Gynaecomastia	5	0	2	
		Breast pain	1	0	0	
		Galactorrhoea	1	0	1	
		Menstruation irregular	1	0	0	
		Metrorrhagia	1	0	0	
		Amenorrhoea	1	0	1	
		Perineal pain	1	0	1	

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Reaction Count	Reproductive system and breast disorders	Erectile dysfunction	2	0	1	
		Testicular disorder	1	0	1	
		Reproductive system and breast disorders	14	0	7	
	Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	0	0	
		Pulmonary fibrosis	1	0	0	
		Pulmonary oedema	1	0	0	
		Apnoea	1	0	1	
		Dyspnoea	6	0	4	
		Hyperventilation	2	0	1	
		Hypoxia	2	0	1	
		Cough	3	0	0	
		Respiratory disorder	1	0	0	
		Dysphonia	1	0	1	
		Respiratory, thoracic and mediastinal disorders	19	0	8	
		Skin and subcutaneous tissue disorders	Angioedema	1	0	1
			Urticaria	6	0	5
			Lichenoid keratosis	1	0	1
	Dermatitis bullous		1	0	1	
	Skin discolouration		1	0	0	
	Yellow skin		1	0	1	
	Stasis dermatitis		1	0	1	
	Erythema		1	0	0	
	Rash erythematous		2	0	1	
	Skin exfoliation		1	0	1	
	Photosensitivity reaction		2	0	2	
	Pruritus		19	0	12	
	Rash		19	0	6	
	Rash maculo-papular		8	0	4	
	Rash morbilliform		1	0	1	
	Rash vesicular		1	0	0	
	Chloasma		1	0	1	
	Erythema nodosum		2	0	1	
	Skin ulcer		1	0	1	
Acne	3		0	2		
Alopecia	4		0	2		
Hyperhidrosis	14		0	2		
Night sweats	1		0	0		
Hair texture abnormal	1		0	0		
Purpura	4		0	0		
Skin and subcutaneous tissue disorders	97		0	46		
Surgical and medical procedures	Drug therapy changed		1	0	1	
	Surgical and medical procedures		1	0	1	

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			Case Group	Death Outcomes	Sole
Reaction Count	Vascular disorders	Peripheral ischaemia	3	0	0
		Hypotension	3	0	1
		Orthostatic hypotension	13	0	7
		Flushing	4	0	2
		Hot flush	3	0	1
		Pallor	1	0	0
		Hypertension	4	1	2
		Arteritis	1	0	0
		Vascular disorders	32	1	13
	Reaction	1001	33	478	