

**Medicine summary - dothiepin (to end January 2009)**

			Case Group	Death Outcomes	Sole	
Case Count			430	14	216	
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	
		<b>Blood and lymphatic system disorders</b>		<b>29</b>	<b>2</b>	<b>9</b>
		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		8	0	5	
	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	
	<b>Cardiac disorders</b>		<b>39</b>	<b>3</b>	<b>16</b>	
	Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0	1	
		Congenital foot malformation	1	0	1	
		Limb reduction defect	1	0	1	
		<b>Congenital, familial and genetic disorders</b>		<b>3</b>	<b>0</b>	<b>3</b>
	Ear and labyrinth disorders	Deafness	1	0	1	
		Hyperacusis	1	0	1	
		Tinnitus	4	0	4	
		Vertigo	1	0	1	

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			Case Group	Death Outcomes	Sole
Reaction Count	Ear and labyrinth disorders	<b>Ear and labyrinth disorders</b>	7	0	7
	Endocrine disorders	Inappropriate antidiuretic hormone secretion	2	0	1
		Hypothyroidism	1	0	0
		<b>Endocrine disorders</b>	3	0	1
	Eye disorders	Xerophthalmia	1	0	1
		Dry eye	1	0	1
		Lacrimal disorder	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	2	0	0
		Visual impairment	12	0	9
		<b>Eye disorders</b>	26	0	17
		Gastrointestinal disorders	Gingivitis	1	0
	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		16	0	11
	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		
Swollen tongue	1	0	1		
Tongue discolouration	1	0	0		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Gastrointestinal disorders	Tongue oedema	2	0	1	
		<b>Gastrointestinal disorders</b>	<b>86</b>	<b>2</b>	<b>50</b>	
	General disorders and administration site conditions	Pyrexia	17	1	9	
		Sudden death	2	2	0	
		Asthenia	4	0	2	
		Fatigue	13	0	5	
		Malaise	6	0	4	
		Gait disturbance	4	0	0	
		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	1	0	1	
		Chest pain	7	0	1	
		Pain	2	0	1	
		Chills	3	0	1	
		Thirst	1	0	0	
		Drug ineffective	10	0	7	
		Therapeutic response decreased	1	0	0	
		Therapeutic response unexpected with drug substitution	2	0	2	
		Drug withdrawal syndrome neonatal	1	0	0	
		<b>General disorders and administration site conditions</b>	<b>81</b>	<b>3</b>	<b>36</b>	
		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		
Hepatitis	8		0	1		
Hepatocellular injury	2		0	0		
<b>Hepatobiliary disorders</b>	<b>47</b>		<b>3</b>	<b>13</b>		
Immune system disorders	Hypersensitivity		1	0	0	
	<b>Immune system disorders</b>	<b>1</b>	<b>0</b>	<b>0</b>		
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		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Infections and infestations	Cystitis	1	0	0	
		<b>Infections and infestations</b>	<b>12</b>	<b>2</b>	<b>6</b>	
	Injury, poisoning and procedural complications	Drug exposure during pregnancy	1	0	0	
		Fall	2	0	0	
		Sunburn	1	0	1	
		Intentional overdose	1	0	1	
		<b>Injury, poisoning and procedural complications</b>	<b>5</b>	<b>0</b>	<b>2</b>	
		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	
	<b>Investigations</b>		<b>19</b>	<b>0</b>	<b>6</b>	
	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	9	0	3	
		Hyperglycaemia	1	0	1	
		<b>Metabolism and nutrition disorders</b>	<b>27</b>	<b>1</b>	<b>11</b>	
	Musculoskeletal and connective tissue disorders	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	
		Back pain	1	0	1	
		<b>Musculoskeletal and connective tissue disorders</b>	<b>25</b>	<b>0</b>	<b>12</b>	

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		Case Group	Death Outcomes	Sole	
Reaction Count	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	2	1	0
		Bronchioloalveolar carcinoma	1	1	0
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>		<b>3</b>	<b>2</b>	<b>0</b>	
Reaction Count	Nervous system disorders	Cerebral haemorrhage	1	0	0
		Transient ischaemic attack	2	0	0
		Facial palsy	1	0	1
		Parosmia	2	0	1
		Encephalopathy	2	0	1
		Headache	17	0	10
		Migraine	3	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	19	0	8
		Hyperreflexia	3	0	0
		Ataxia	9	0	4
		Cerebellar syndrome	2	0	1
		Coordination abnormal	2	0	0
		Coma	2	0	1
		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	19	0	9
		Hyperaesthesia	1	0	1
		Paraesthesia	18	0	10
		Dysgeusia	2	0	2
		Hypoaesthesia	2	0	2
		Restless legs syndrome	1	0	1
		Sensory disturbance	1	0	1

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			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	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	4	0	0
		Neuropathy peripheral	2	0	2
		Grand mal convulsion	6	0	4
		Convulsion	18	0	5
		<b>Nervous system disorders</b>	<b>196</b>	<b>0</b>	<b>88</b>
	Pregnancy, puerperium and perinatal conditions	Intra-uterine death	2	1	1
		Foetal growth retardation	1	1	0
		<b>Pregnancy, puerperium and perinatal conditions</b>	<b>3</b>	<b>2</b>	<b>1</b>
	Psychiatric disorders	Agitation	21	1	15
		Anxiety	9	0	3
		Nervousness	2	0	2
		Neurosis	1	0	0
		Catatonia	2	0	1
		Restlessness	1	0	1
		Bruxism	1	0	0
		Communication disorder	1	0	1
		Confusional state	24	2	8
		Disorientation	1	0	1
		Delirium	2	0	1
		Depression	5	0	3
		Depersonalisation	3	0	1
		Delusion	1	0	0
		Hallucination	15	1	8
		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		3	0	3	
Psychotic disorder		2	0	0	
Libido decreased	2	0	1		
Loss of libido	2	0	0		

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			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Insomnia	16	0	11
		Nightmare	11	0	6
		Suicidal ideation	2	0	1
		Suicide attempt	2	0	1
		<b>Psychiatric disorders</b>	<b>153</b>	<b>5</b>	<b>80</b>
	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	5	0	1
		Chromaturia	1	0	0
		Polyuria	2	0	2
		<b>Renal and urinary disorders</b>	<b>20</b>	<b>2</b>	<b>8</b>
	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
		Erectile dysfunction	2	0	1
		Testicular disorder	1	0	1
		<b>Reproductive system and breast disorders</b>	<b>14</b>	<b>0</b>	<b>7</b>
	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
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>19</b>	<b>0</b>	<b>8</b>
	Skin and subcutaneous tissue disorders	Angioedema	1	0	1
		Periorbital oedema	1	0	0
		Urticaria	6	0	5
		Lichenoid keratosis	1	0	1
		Dermatitis bullous	1	0	1

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Reaction Count	Skin and subcutaneous tissue disorders	Skin discolouration	1	0	0
		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
	<b>Skin and subcutaneous tissue disorders</b>	<b>97</b>	<b>0</b>	<b>45</b>	
Surgical and medical procedures	Drug therapy changed	1	0	1	
	<b>Surgical and medical procedures</b>	<b>1</b>	<b>0</b>	<b>1</b>	
Vascular disorders	Peripheral ischaemia	3	0	0	
	Hypotension	3	0	1	
	Orthostatic hypotension	10	0	5	
	Flushing	4	0	2	
	Hot flush	3	0	1	
	Pallor	1	0	0	
	Hypertension	4	1	2	
	Arteritis	1	0	0	
	<b>Vascular disorders</b>	<b>29</b>	<b>1</b>	<b>11</b>	
<b>Reaction</b>		<b>945</b>	<b>28</b>	<b>438</b>	