

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

DOTHIPIIN HYDROCHLORIDE		Layer 1 of 1		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		422	14	211
<b>- Occurrences of Medicine</b>		448	15	211
<b>- Reactions Related to Medicine</b>		927	28	432
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
Cardiac disorders	Neutropenia	1	0	1
	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
	Palpitations	8	0	5
	Aortic valve incompetence	1	0	0
	Angina pectoris	2	0	1
	Myocardial infarction	1	1	0
	Right ventricular failure	1	0	1
Cardiomyopathy	1	0	1	
Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0	1

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Congenital, familial and genetic disorders	Congenital foot malformation	1	0	1
	Limb reduction defect	1	0	1
Ear and labyrinth disorders	Deafness	1	0	1
	Hyperacusis	1	0	1
	Tinnitus	4	0	4
	Vertigo	1	0	1
Endocrine disorders	Inappropriate antidiuretic hormone secretion	2	0	1
	Hypothyroidism	1	0	0
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 disturbance	12	0	9
	Gastrointestinal disorders	Gingivitis	1	0
Haematemesis		2	0	0
Melaena		1	0	0
Enteritis		1	0	0
Diarrhoea		5	0	5
Constipation		7	0	5
Dyspepsia		4	0	2
Abdominal distension		1	0	0
Flatulence		1	0	1
Abdominal pain		13	0	9
Nausea		15	0	11
Vomiting		8	0	6
Duodenal ulcer haemorrhage		1	1	0
Duodenal ulcer perforation		1	0	0
Gastric ulcer perforation		1	0	0

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Gastrointestinal disorders	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
	Tongue discolouration	1	0	0
	Tongue oedema	2	0	1
General disorders and administration site conditions	Chills	3	0	1
	Pyrexia	17	1	9
	Sudden death	2	2	0
	Asthenia	4	0	2
	Fatigue	12	0	5
	Malaise	6	0	4
	Gait disturbance	5	0	0
	Influenza like illness	1	0	0
	Thirst	1	0	0
	Enanthema	1	0	0
	Face oedema	2	0	2
	Gravitational oedema	2	0	0
	Oedema peripheral	1	0	1
	Chest pain	7	0	1
	Pain	2	0	1
	Drug ineffective	9	0	7
	Drug withdrawal syndrome	3	0	3
	Drug withdrawal syndrome neonatal	1	0	0
Therapeutic response decreased	1	0	0	
Therapeutic response unexpected with drug substitution	1	0	1	
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

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Hepatobiliary disorders	Hepatosplenomegaly	1	1	0
	Hepatitis	8	0	1
	Hepatocellular damage	2	0	0
Immune system disorders	Hypersensitivity	1	0	0
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
Injury, poisoning and procedural complications	Fall	2	0	0
	Sunburn	1	0	1
	Intentional overdose	1	0	1
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
Metabolism and nutrition disorders	Anorexia	7	0	5
	Decreased appetite	1	0	0
	Increased appetite	1	0	1
	Feeding disorder neonatal	1	0	0
	Hypercalcaemia	1	0	0
	Hypochloraemia	2	0	0
	Polydipsia	1	0	1

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Metabolism and nutrition disorders	Hypokalaemia	3	1	0
	Hyponatraemia	9	0	3
	Hyperglycaemia	1	0	1
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
	Back pain	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	2	1	0
	Bronchioloalveolar carcinoma	1	1	0
Nervous system disorders	Cerebral haemorrhage	1	0	0
	Transient ischaemic attack	1	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
	Tremor	20	0	8
	Hyperreflexia	3	0	0
	Cerebellar syndrome	2	0	1
	Coordination abnormal	11	0	4
Coma	2	0	1	
Aphasia	1	0	0	

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Nervous system disorders	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	17	0	8
	Hyperaesthesia	1	0	1
	Hypoaesthesia	1	0	1
	Paraesthesia	17	0	9
	Dysgeusia	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	4	0	0
	Neuropathy peripheral	1	0	1
Grand mal convulsion	6	0	4	
Convulsion	18	0	5	
Pregnancy, puerperium and perinatal conditions	Intra-uterine death	2	1	1
	Foetal growth retardation	1	1	0
Psychiatric disorders	Neurosis	1	0	0
	Agitation	21	1	15
	Anxiety	9	0	3
	Nervousness	2	0	2
	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

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Psychiatric disorders	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
	Mood altered	1	0	0
	Aggression	4	0	2
	Homicidal ideation	1	0	1
	Paranoia	5	1	2
	Psychotic disorder	2	0	0
	Libido decreased	2	0	1
	Loss of libido	1	0	0
	Insomnia	16	0	11
	Nightmare	10	0	6
	Suicidal ideation	2	0	1
	Suicide attempt	2	0	1
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
Reproductive system and breast disorders	Gynaecomastia	5	0	2
	Breast pain	1	0	0
	Galactorrhoea	1	0	1
	Menstruation irregular	1	0	0
	Amenorrhoea	1	0	1
	Metrorrhagia	1	0	0

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Reproductive system and breast disorders	Perineal pain	2	0	2
	Erectile dysfunction	2	0	1
	Testicular disorder	1	0	1
Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	0	0
	Pulmonary fibrosis	1	0	0
	Pulmonary oedema	1	0	0
	Apnoea	1	0	1
	Dyspnoea	5	0	3
	Hyperventilation	2	0	1
	Hypoxia	2	0	1
	Cough	4	0	0
	Respiratory disorder	1	0	0
	Dysphonia	1	0	1
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
	Skin discolouration	1	0	0
	Erythema	1	0	0
	Rash erythematous	2	0	1
	Skin exfoliation	1	0	1
	Photosensitivity reaction	2	0	2
	Pruritus	19	0	12
	Rash	21	0	8
	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
	Acne	3	0	2
	Alopecia	4	0	2
	Hyperhidrosis	14	0	2
Night sweats	1	0	0	
Hair texture abnormal	1	0	0	





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Skin and subcutaneous tissue (	Purpura	5	0	0
Surgical and medical procedure	Drug therapy changed	1	0	1
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