

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

FLUPHENAZINE DECANOATE + FLUPHENAZINE NOS		Layer 1 of 1		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		214	15	99
<b>- Occurrences of Medicine</b>		232	16	99
<b>- Reactions Related to Medicine</b>		417	38	175
Blood and lymphatic system disorders	Agranulocytosis	3	1	0
	Anaemia	2	1	0
	Bone marrow failure	1	0	0
	Eosinophilia	1	0	0
	Leukocytosis	2	0	0
	Leukopenia	3	0	0
	Lymphadenopathy	1	1	0
	Neutropenia	4	2	0
	Thrombocytopenia	1	0	0
Cardiac disorders	Cardiac arrest	1	1	0
	Cardiomyopathy	1	1	0
	Cyanosis	1	0	0
	Myocardial infarction	1	1	0
	Myocarditis	1	0	0
	Tachycardia	8	0	2
Congenital, familial and genetic disorders	Anencephaly	1	0	0
	Congenital genitourinary abnormality	1	1	1
	Heart disease congenital	1	0	1
	Polydactyly	1	0	0
	Skull malformation	1	0	0
	Talipes	1	0	1
	Trisomy 21	1	0	1
Endocrine disorders	Diabetes insipidus	1	0	0
Eye disorders	Accommodation disorder	1	0	0
	Cataract	1	0	0
	Eye disorder	1	0	0
	Mydriasis	1	0	1
	Oculogyration	4	0	4

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Eye disorders	Retinal pigmentation	1	0	0
	Visual disturbance	3	0	2
Gastrointestinal disorders	Constipation	4	0	2
	Dry mouth	3	0	1
	Dyspepsia	1	0	1
	Dysphagia	3	0	2
	Faecal incontinence	1	0	1
	Ileus paralytic	1	0	0
	Nausea	1	0	1
	Salivary hypersecretion	9	0	3
	Tongue oedema	1	0	1
	Vomiting	2	0	0
General disorders and administration site conditions	Asthenia	4	0	3
	Face oedema	1	0	0
	Fatigue	1	0	1
	Gait disturbance	2	0	1
	Injection site reaction	4	0	4
	Oedema	3	0	3
	Pain	1	0	1
	Pyrexia	11	1	2
	Sudden death	8	8	0
	Thirst	1	0	1
Hepatobiliary disorders	Hepatic function abnormal	1	0	0
	Hepatitis cholestatic	1	0	0
	Jaundice	1	0	0
Infections and infestations	Pharyngitis	2	1	0
	Rhinitis	1	0	0
	Sepsis	1	1	0
Injury, poisoning and procedural complications	Drug exposure during pregnancy	1	0	1
Investigations	Blood alkaline phosphatase increased	1	0	1
	Blood creatine phosphokinase increased	3	0	0
	Drug level increased	1	1	0
	Haemoglobin decreased	1	0	1
	Weight increased	2	0	1
Metabolism and nutrition disorders	Cachexia	1	0	0

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Metabolism and nutrition disorders	Dehydration	2	0	1
	Hyperchloraemia	1	0	0
	Hypernatraemia	2	0	0
	Hypokalaemia	2	0	0
	Hyponatraemia	3	1	1
	Polydipsia	1	0	0
Musculoskeletal and connective tissue disorders	Arthritis	2	0	2
	Back pain	1	0	1
	Muscle spasms	1	0	1
	Rhabdomyolysis	1	0	1
	Systemic lupus erythematosus	1	1	0
Neoplasms benign, malignant and unspecified	Breast cancer female	2	0	1
Nervous system disorders	Brain oedema	1	0	1
	Choreoathetosis	1	0	1
	Consciousness fluctuating	3	1	0
	Convulsion	1	0	0
	Coordination abnormal	5	0	3
	Dizziness	1	1	0
	Dysarthria	4	0	2
	Dyskinesia	12	0	5
	Dystonia	15	0	7
	Extrapyramidal disorder	40	1	16
	Grand mal convulsion	2	0	0
	Headache	1	0	1
	Hyperkinesia	12	0	10
	Hyperreflexia	1	0	1
	Hypertonia	9	0	3
	Hypoaesthesia	1	0	0
	Hypokinesia	3	0	2
	Hypotonia	1	0	0
	Neuroleptic malignant syndrome	17	0	5
	Neuropathy peripheral	1	0	0
	Paraesthesia	2	0	1
	Paralysis	2	0	2
Paresis	1	0	1	

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Nervous system disorders	Somnolence	5	0	2
	Speech disorder	1	0	1
	Syncope	2	1	1
	Tardive dyskinesia	21	1	15
	Tremor	22	2	13
Pregnancy, puerperium and perinatal condi	Intra-uterine death	1	1	0
Psychiatric disorders	Abnormal behaviour	1	0	0
	Aggression	1	0	0
	Agitation	1	0	1
	Apathy	1	0	0
	Confusional state	3	1	1
	Delirium	2	0	1
	Depersonalisation	1	0	0
	Depression	1	0	1
	Hallucination	2	1	1
	Insomnia	2	0	2
	Libido decreased	1	0	0
	Personality disorder	2	0	2
	Schizophreniform disorder	1	0	0
	Staring	1	0	1
	Suicide attempt	1	1	0
Thinking abnormal	1	0	1	
Renal and urinary disorders	Micturition disorder	1	0	0
	Polyuria	1	0	0
	Renal failure acute	1	0	0
	Renal impairment	1	0	0
	Urinary incontinence	3	0	1
	Urinary retention	2	0	0
Reproductive system and breast disorders	Amenorrhoea	1	0	0
	Breast enlargement	1	0	0
	Ejaculation failure	3	0	0
	Erectile dysfunction	2	0	0
	Galactorrhoea	2	0	1
	Gynaecomastia	1	0	1
	Priapism	1	0	0



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Respiratory, thoracic and mediastinal disorders	Dysphonia	1	0	1
	Hyperventilation	2	1	0
	Stridor	1	0	0
Skin and subcutaneous tissue disorders	Alopecia	1	0	1
	Dermatitis psoriasiform	2	0	2
	Hyperhidrosis	2	0	0
	Photosensitivity allergic reaction	1	0	1
	Photosensitivity reaction	3	1	0
	Pruritus	3	0	2
	Rash	5	0	1
	Rash erythematous	3	0	3
	Rash maculo-papular	1	0	0
	Seborrhoea	1	0	0
	Skin disorder	1	0	1
	Systemic lupus erythematosus rash	1	1	0
	Vascular disorders	Aneurysm	1	1
Hot flush		1	0	0
Hypertension		4	0	2
Hypotension		2	0	1
Orthostatic hypotension		2	0	0