

## Medicine summary - Antipsychotics- fluphenazines

			Case Group	Death Outcomes	Sole
Case Count			263	15	122
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	1	0
		Aplastic anaemia	1	0	0
		Bone marrow failure	1	0	0
		Thrombocytopenia	1	0	0
		Lymphadenopathy	1	1	0
		Eosinophilia	1	0	0
		Leukocytosis	3	0	0
		Leukopenia	3	0	0
		Agranulocytosis	4	1	0
		Neutropenia	4	2	0
		<b>Blood and lymphatic system disorders</b>	<b>21</b>	<b>5</b>	<b>0</b>
	Cardiac disorders	Bradycardia	1	0	0
		Tachycardia	8	0	2
		Cardiac arrest	1	1	0
		Cyanosis	1	0	0
		Myocardial infarction	1	1	0
		Cardiomyopathy	1	1	0
		Myocarditis	1	0	0
		<b>Cardiac disorders</b>	<b>14</b>	<b>3</b>	<b>2</b>
	Congenital, familial and genetic disorders	Heart disease congenital	1	0	1
		Trisomy 21	1	0	1
		Multiple congenital abnormalities	1	0	0
		Anal atresia	1	0	0
		Cleft palate	1	0	0
		Cleft lip	1	0	0
		Polydactyly	1	0	0
		Talipes	1	0	1
		Skull malformation	1	0	0
		Anencephaly	1	0	0
		Congenital nystagmus	1	0	0
		Congenital genitourinary abnormality	1	1	1
		Hypospadias	1	0	0

 Outcome Description

 (Causality possible,Causality probable,Causality certain)

 Suspect Type

 Suspect Code

 Case Group

 GM

 (Fluphenazine Decanoate,Fluphenazine Enanthate,Fluphenazine Hydrochloride,Fluphenazine Nos)

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Reaction Count	Congenital, familial and genetic disorders	<b>Congenital, familial and genetic disorders</b>	<b>13</b>	<b>1</b>	<b>4</b>
	Endocrine disorders	Diabetes insipidus	1	0	0
		<b>Endocrine disorders</b>	<b>1</b>	<b>0</b>	<b>0</b>
	Eye disorders	Cataract	1	0	0
		Eye disorder	1	0	0
		Oculogyric crisis	7	0	6
		Mydriasis	1	0	1
		Retinal pigmentation	1	0	0
		Retinal haemorrhage	1	0	0
		Accommodation disorder	1	0	0
		Visual impairment	4	0	3
		<b>Eye disorders</b>	<b>17</b>	<b>0</b>	<b>10</b>
		Gastrointestinal disorders	Constipation	4	0
	Ileus paralytic		1	0	0
	Dyspepsia		1	0	1
	Dysphagia		5	0	3
	Faecal incontinence		1	0	1
	Nausea		3	0	2
	Vomiting		3	0	0
	Intestinal perforation		1	0	0
	Dry mouth		3	0	1
	Salivary hypersecretion		10	0	3
	Tongue oedema		1	0	1
	<b>Gastrointestinal disorders</b>		<b>33</b>	<b>0</b>	<b>14</b>
	General disorders and administration site conditions		Injection site reaction	4	0
		Pyrexia	13	1	3
		Sudden death	8	8	0
		Asthenia	4	0	3
		Fatigue	1	0	1
		Gait disturbance	2	0	1
		Face oedema	1	0	0
		Oedema	3	0	3
		Chest pain	1	0	0

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Reaction Count	General disorders and administration site conditions	Pain	1	0	1
		Chills	1	0	1
		Feeling abnormal	1	0	1
		Thirst	1	0	1
		<b>General disorders and administration site conditions</b>	<b>41</b>	<b>9</b>	<b>19</b>
	Hepatobiliary disorders	Hepatitis cholestatic	3	0	0
		Jaundice	2	0	1
		Hepatic function abnormal	1	0	0
		Hepatomegaly	1	0	0
		Hepatitis	1	0	0
		<b>Hepatobiliary disorders</b>	<b>8</b>	<b>0</b>	<b>1</b>
	Infections and infestations	Sepsis	1	1	0
		Pharyngitis	2	1	0
		Rhinitis	1	0	0
		<b>Infections and infestations</b>	<b>4</b>	<b>2</b>	<b>0</b>
	Injury, poisoning and procedural complications	Drug exposure during pregnancy	1	0	1
		Medication error	1	0	1
		<b>Injury, poisoning and procedural complications</b>	<b>2</b>	<b>0</b>	<b>2</b>
	Investigations	Blood creatine phosphokinase increased	5	0	1
		Blood alkaline phosphatase increased	1	0	1
		Haemoglobin decreased	1	0	1
		Weight increased	2	0	1
		Drug level increased	1	1	0
		<b>Investigations</b>	<b>10</b>	<b>1</b>	<b>4</b>
	Metabolism and nutrition disorders	Cachexia	1	0	0
		Hyperchloraemia	1	0	0
		Polydipsia	1	0	0
		Hypokalaemia	2	0	0
Hypernatraemia		2	0	0	
Hyponatraemia		3	1	1	
Dehydration		2	0	1	
<b>Metabolism and nutrition disorders</b>		<b>12</b>	<b>1</b>	<b>2</b>	

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Reaction Count			Case Group	Death Outcomes	Sole
	Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	1	1	0
		Arthritis	2	0	2
		Muscle spasms	1	0	1
		Torticollis	1	0	1
		Rhabdomyolysis	1	0	1
		Back pain	1	0	1
		<b>Musculoskeletal and connective tissue disorders</b>	<b>7</b>	<b>1</b>	<b>6</b>
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	2	0	1
		<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>2</b>	<b>0</b>	<b>1</b>
	Nervous system disorders	Headache	2	0	1
		Brain oedema	1	0	1
		Amnesia	1	0	1
		Choreoathetosis	2	0	2
		Dyskinesia	13	0	6
		Extrapyramidal disorder	45	1	21
		Hyperkinesia	12	0	10
		Hypokinesia	3	0	2
		Tardive dyskinesia	24	1	16
		Dystonia	23	0	14
		Opisthotonus	1	0	1
		Paralysis	2	0	2
		Paresis	1	0	1
		Tremor	26	2	15
		Hyperreflexia	1	0	1
		Ataxia	5	0	3
		Coma	1	0	0
		Consciousness fluctuating	3	1	0
Somnolence		5	0	2	
Syncope		3	1	2	
Dizziness	1	1	0		
Myoclonus	1	0	0		
Paraesthesia	2	0	1		

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Reaction Count	Nervous system disorders	Hypoaesthesia	1	0	0
		Sensory disturbance	1	0	0
		Dysarthria	4	0	2
		Speech disorder	2	0	1
		Hypertonia	11	0	4
		Hypotonia	1	0	0
		Neuroleptic malignant syndrome	21	0	6
		Neuropathy peripheral	1	0	0
		Grand mal convulsion	2	0	0
		Convulsion	4	0	3
		<b>Nervous system disorders</b>	<b>226</b>	<b>7</b>	<b>118</b>
	Pregnancy, puerperium and perinatal conditions	Intra-uterine death	1	1	0
		<b>Pregnancy, puerperium and perinatal conditions</b>	<b>1</b>	<b>1</b>	<b>0</b>
	Psychiatric disorders	Agitation	3	0	3
		Catatonia	1	0	0
		Bruxism	1	0	1
		Confusional state	4	1	2
		Delirium	2	0	1
		Depression	1	0	1
		Depersonalisation	1	0	0
		Hallucination	2	1	1
		Thinking abnormal	3	0	3
		Apathy	1	0	0
		Aggression	1	0	0
		Personality disorder	1	0	1
		Abnormal behaviour	1	0	0
		Staring	1	0	1
		Schizophreniform disorder	1	0	0
		Libido decreased	1	0	0
		Insomnia	3	0	3
		Sleep disorder	1	0	0
		Suicide attempt	1	1	0

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Reaction Count	Psychiatric disorders	<b>Psychiatric disorders</b>	<b>30</b>	<b>3</b>	<b>17</b>
	Renal and urinary disorders	Renal failure acute	1	0	0
		Renal impairment	1	0	0
		Micturition disorder	1	0	0
		Urinary incontinence	3	0	1
		Urinary retention	2	0	0
		Polyuria	1	0	0
		<b>Renal and urinary disorders</b>	<b>9</b>	<b>0</b>	<b>1</b>
		Reproductive system and breast disorders	Breast enlargement	1	0
	Gynaecomastia		1	0	1
	Galactorrhoea		2	0	1
	Amenorrhoea		1	0	0
	Ejaculation failure		3	0	0
	Erectile dysfunction		2	0	0
	Priapism		1	0	0
	<b>Reproductive system and breast disorders</b>		<b>11</b>	<b>0</b>	<b>2</b>
	Respiratory, thoracic and mediastinal disorders	Hyperventilation	2	1	0
		Dysphonia	1	0	1
		Stridor	1	0	0
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>4</b>	<b>1</b>	<b>1</b>
	Skin and subcutaneous tissue disorders	Skin disorder	1	0	1
		Rash erythematous	2	0	2
		Photosensitivity allergic reaction	1	0	1
		Photosensitivity reaction	3	1	0
		Pruritus	6	0	2
		Dermatitis psoriasiform	1	0	1
		Rash	8	0	1
		Rash maculo-papular	1	0	0
		Systemic lupus erythematosus rash	1	1	0
		Skin ulcer	3	0	0
		Alopecia	1	0	1
		Hyperhidrosis	2	0	0
	Seborrhoea	1	0	0	

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Reaction Count	Skin and subcutaneous tissue disorders	<b>Skin and subcutaneous tissue disorders</b>	<b>31</b>	<b>2</b>	<b>9</b>
	Vascular disorders	Aneurysm	<b>1</b>	<b>1</b>	<b>0</b>
		Hypotension	<b>2</b>	<b>0</b>	<b>1</b>
		Orthostatic hypotension	<b>3</b>	<b>0</b>	<b>0</b>
		Thrombosis	<b>1</b>	<b>0</b>	<b>0</b>
		Hot flush	<b>1</b>	<b>0</b>	<b>0</b>
		Hypertension	<b>6</b>	<b>0</b>	<b>3</b>
		<b>Vascular disorders</b>	<b>14</b>	<b>1</b>	<b>4</b>
	<b>Reaction</b>		<b>511</b>	<b>38</b>	<b>217</b>

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