

## **Medicine summary - Antipsychotics- haloperidol**

		Case Group	Death Outcomes	Sole
Case Count		<b>748</b>	<b>22</b>	<b>330</b>
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	0 0
		Bone marrow failure	1	0 0
		Pancytopenia	4	0 1
		Haemolytic anaemia	1	0 0
		Thrombocytopenia	2	0 0
		Lymphadenopathy	1	0 0
		Splenomegaly	2	0 0
		Eosinophilia	1	0 0
		Leukocytosis	9	1 3
		Leukopenia	3	0 0
		Lymphopenia	2	0 1
		Agranulocytosis	4	0 0
		Neutropenia	6	0 0
		<b>Blood and lymphatic system disorders</b>	<b>38</b>	<b>1 5</b>
Cardiac disorders	Cardiac disorders	Brugada syndrome	1	1 0
		Arrhythmia	2	1 0
		Bradycardia	2	0 0
		Extrasystoles	2	0 1
		Tachycardia	22	0 1
		Cardiac arrest	4	3 1
		Torsade de pointes	1	0 0
		Ventricular arrhythmia	1	0 1
		Ventricular fibrillation	2	0 1
		Ventricular tachycardia	1	0 0
		Cyanosis	8	0 5
		Coronary artery disease	1	1 0
		Myocardial infarction	1	0 0
		Cardiac failure	3	1 0
		Cardiomyopathy	4	0 0
Congenital, familial and genetic disorders	Congenital, familial and genetic disorders	Myocarditis	5	0 0
		<b>Cardiac disorders</b>	<b>60</b>	<b>7 10</b>
Congenital, familial and genetic disorders		Vascular malformation peripheral	1	0 0

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	Congenital, familial and genetic disorders	Congenital hand malformation	1	0	0
		Polydactyly	1	0	0
		Congenital brain damage	1	0	0
		Tourette's disorder	1	0	1
		<b>Congenital, familial and genetic disorders</b>	<b>5</b>	<b>0</b>	<b>1</b>
	Ear and labyrinth disorders	Tinnitus	1	0	0
		<b>Ear and labyrinth disorders</b>	<b>1</b>	<b>0</b>	<b>0</b>
	Endocrine disorders	Diabetes insipidus	2	1	0
		<b>Endocrine disorders</b>	<b>2</b>	<b>1</b>	<b>0</b>
	Eye disorders	Cataract	1	0	0
		Periorbital oedema	1	1	0
		Glaucoma	1	0	1
		Conjunctivitis	2	0	1
		Uveitis	1	0	0
		Blepharospasm	1	0	1
		Eye movement disorder	1	0	1
		Oculogyric crisis	<b>46</b>	<b>0</b>	<b>25</b>
		Miosis	1	0	1
		Mydriasis	1	0	0
		Pupillary reflex impaired	1	0	0
		Diplopia	1	0	0
		Vision blurred	1	0	1
		Visual impairment	6	0	4
		<b>Eye disorders</b>	<b>65</b>	<b>1</b>	<b>35</b>
	Gastrointestinal disorders	Rectal tenesmus	1	0	1
		Tooth discolouration	1	0	0
		Gingival hyperplasia	1	0	1
		Gingivitis	2	0	2
		Haematemesis	2	0	1
		Oesophagitis	1	0	0
		Diarrhoea	2	0	0
		Constipation	5	1	2
		Dyspepsia	1	0	1

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Reaction Count			Case Group	Death Outcomes	Sole
Gastrointestinal disorders	Abdominal pain		2	0	0
	Dysphagia		5	0	4
	Faecal incontinence		2	0	1
	Nausea		12	0	5
	Retching		1	0	1
	Vomiting		11	0	4
	Oesophagitis ulcerative		1	0	0
	Cheilitis		1	1	0
	Oedema mouth		1	0	1
	Mouth ulceration		3	0	1
	Stomatitis		1	0	0
	Dry mouth		2	1	0
	Salivary hypersecretion		17	0	8
	Salivary gland enlargement		1	0	0
	Glossitis		1	0	0
	Swollen tongue		3	0	2
	Tongue oedema		9	1	6
	<b>Gastrointestinal disorders</b>		<b>89</b>	<b>4</b>	<b>41</b>
General disorders and administration site conditions	Hypothermia		1	0	0
	Pyrexia		55	6	13
	Sudden death		6	6	1
	Asthenia		3	0	2
	Fatigue		6	1	1
	Malaise		3	1	1
	Abasia		1	1	0
	Gait disturbance		13	0	8
	Condition aggravated		3	0	1
	Irritability		1	0	0
	Face oedema		6	0	0
	Generalised oedema		1	0	0
	Gravitational oedema		1	0	0
	Oedema		2	0	0
	Oedema peripheral		2	0	0

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Reaction Count			Case Group	Death Outcomes	Sole
	General disorders and administration site conditions	Chest pain	1	0	0
		Pain	6	0	5
		Chills	5	0	2
		Feeling abnormal	1	0	0
		Feeling jittery	1	0	0
		Drug interaction	1	0	0
		Drug ineffective	4	0	1
		Drug withdrawal syndrome neonatal	2	0	0
		<b>General disorders and administration site conditions</b>	<b>125</b>	<b>15</b>	<b>35</b>
	Hepatobiliary disorders	Hepatitis cholestatic	1	0	1
		Jaundice	13	1	3
		Hepatic function abnormal	15	2	2
		Hepatomegaly	2	0	0
		Hepatic steatosis	1	0	0
		Hepatitis	2	0	1
		<b>Hepatobiliary disorders</b>	<b>34</b>	<b>3</b>	<b>7</b>
	Infections and infestations	Abscess	1	0	0
		Pneumonia	5	1	1
		Sepsis	2	1	0
		Pharyngitis	5	0	2
		Upper respiratory tract infection	1	0	0
		Urinary tract infection	2	0	0
		<b>Infections and infestations</b>	<b>16</b>	<b>2</b>	<b>3</b>
	Injury, poisoning and procedural complications	Drug exposure during pregnancy	3	0	1
		Fall	3	0	1
		Sunburn	1	0	1
		Medication error	1	0	0
		Overdose	2	0	0
		<b>Injury, poisoning and procedural complications</b>	<b>10</b>	<b>0</b>	<b>3</b>
	Investigations	Ejection fraction decreased	1	0	0
		Electrocardiogram QT prolonged	2	1	0
		Electrocardiogram abnormal	1	0	1

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Investigations	Blood prolactin increased	1	0	1	
	Blood creatine phosphokinase increased	28	1	11	
	Troponin increased	1	0	0	
	Blood alkaline phosphatase increased	2	0	0	
	Prothrombin level decreased	1	0	0	
	Red blood cell sedimentation rate increased	2	0	0	
	Platelet aggregation abnormal	1	0	0	
	Alanine aminotransferase increased	1	0	0	
	Gamma-glutamyltransferase increased	1	0	0	
	Liver function test abnormal	3	0	0	
	Weight decreased	5	0	0	
	Weight increased	2	0	1	
	C-reactive protein increased	1	0	1	
	<b>Investigations</b>	<b>53</b>	<b>2</b>	<b>15</b>	
Metabolism and nutrition disorders	Decreased appetite	6	3	1	
	Tetany	1	0	0	
	Hypomagnesaemia	1	1	0	
	Hypochloraemia	1	1	0	
	Hypokalaemia	1	0	0	
	Hypernatraemia	2	0	0	
	Hyponatraemia	11	1	3	
	Dehydration	7	2	0	
	Hyperglycaemia	1	1	0	
	Hypoglycaemia	1	0	1	
	Gout	1	0	0	
	<b>Metabolism and nutrition disorders</b>	<b>33</b>	<b>9</b>	<b>5</b>	
Musculoskeletal and connective tissue disorders	Arthralgia	1	0	1	
	Joint stiffness	1	0	0	
	Myalgia	2	0	2	
	Muscle spasms	2	0	1	
	Muscle twitching	9	0	7	
	Muscle rigidity	5	0	2	
	Torticollis	8	0	5	

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Case Group	Death Outcomes	Sole
Musculoskeletal and connective tissue disorders		
Trismus	2	0
Myopathy	1	0
Rhabdomyolysis	1	0
Musculoskeletal stiffness	7	0
Back pain	3	0
<b>Musculoskeletal and connective tissue disorders</b>	<b>42</b>	<b>0</b>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer female	1	0
Hepatic neoplasm malignant	1	0
Malignant melanoma	1	0
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>3</b>	<b>0</b>
Nervous system disorders		
Cerebral infarction	1	0
Cerebrovascular accident	1	1
Haemorrhage intracranial	1	1
Tongue paralysis	1	0
Encephalopathy	1	0
Headache	9	0
Dementia	2	0
Amnesia	1	0
Choreoathetosis	5	0
Akathisia	2	0
Bradykinesia	7	0
Dyskinesia	24	0
Extrapyramidal disorder	87	1
Hyperkinesia	17	0
Hypokinesia	5	0
Movement disorder	1	0
Tardive dyskinesia	15	0
Dystonia	157	0
Opisthotonus	8	0
Hemiparesis	1	1
Paresis	1	0
Cogwheel rigidity	5	0

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Case Group	Death Outcomes	Sole
Parkinsonian gait	3	0
Parkinsonism	6	1
Tremor	40	0
Hyperreflexia	5	1
Hyporeflexia	2	0
Ataxia	8	0
Nystagmus	1	0
Coma	12	1
Aphasia	2	0
Altered state of consciousness	1	0
Consciousness fluctuating	8	2
Depressed level of consciousness	3	1
Lethargy	1	0
Sedation	2	0
Somnolence	30	2
Stupor	2	1
Syncope	9	0
Dizziness	10	0
Drooling	1	0
Myoclonus	1	0
Unresponsive to stimuli	1	0
Formication	1	0
Paraesthesia	3	0
Hypoesthesia	1	0
Dysarthria	7	1
Speech disorder	13	0
Upper motor neurone lesion	1	1
Hypertonia	57	5
Hypotonia	3	1
Neuroleptic malignant syndrome	71	5
Serotonin syndrome	2	0
Muscle contractions involuntary	1	0
Neuritis	1	0

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			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Neuropathy peripheral	1	0	0
		Grand mal convolution	9	0	1
		Convulsion	20	3	7
		Convulsions local	1	0	0
		Brain injury	1	1	1
		<b>Nervous system disorders</b>	<b>693</b>	<b>30</b>	<b>348</b>
	Pregnancy, puerperium and perinatal conditions	Hyperemesis gravidarum	1	0	0
		Premature baby	3	0	0
		Small for dates baby	1	0	0
		Jaundice neonatal	2	0	0
		<b>Pregnancy, puerperium and perinatal conditions</b>	<b>7</b>	<b>0</b>	<b>0</b>
	Psychiatric disorders	Agitation	28	3	14
		Anxiety	10	0	7
		Nervousness	1	0	0
		Tension	1	0	0
		Catatonia	11	0	6
		Restlessness	1	0	1
		Bruxism	1	0	0
		Posturing	1	0	1
		Confusional state	48	3	18
		Disorientation	1	0	0
		Delirium	10	0	0
		Depression	1	0	0
		Delusion	2	0	0
		Hallucination	8	0	2
		Thinking abnormal	5	0	1
		Mania	4	0	1
		Euphoric mood	1	0	0
		Frustration	1	0	0
		Apathy	1	0	0
		Aggression	5	0	2
		Homicidal ideation	1	0	0

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Reaction Count			Case Group	Death Outcomes	Sole
Psychiatric disorders	Paranoia		3	0	1
	Personality disorder		1	0	0
	Withdrawal syndrome		2	0	1
	Psychotic disorder		3	0	0
	Insomnia		9	0	2
	Sleep talking		1	0	0
	Sleep disorder		1	0	1
	Suicidal ideation		2	0	0
	Suicide attempt		2	0	0
	<b>Psychiatric disorders</b>		<b>166</b>	<b>6</b>	<b>58</b>
Renal and urinary disorders	Anuria		1	0	0
	Renal failure acute		2	1	0
	Renal impairment		2	0	0
	Dysuria		2	1	0
	Incontinence		1	0	0
	Urinary incontinence		7	1	4
	Urinary retention		4	0	1
	<b>Renal and urinary disorders</b>		<b>19</b>	<b>3</b>	<b>5</b>
Reproductive system and breast disorders	Galactorrhoea		2	0	1
	Ejaculation failure		2	0	1
	Priapism		1	0	1
	Infertility female		2	0	2
	<b>Reproductive system and breast disorders</b>		<b>7</b>	<b>0</b>	<b>5</b>
Respiratory, thoracic and mediastinal disorders	Neonatal respiratory distress syndrome		2	0	0
	Neonatal respiratory failure		1	0	0
	Pulmonary embolism		1	1	0
	Apnoea		1	1	1
	Dyspnoea		12	1	7
	Hyperventilation		4	1	2
	Respiratory arrest		3	0	0
	Respiratory depression		3	0	1
	Respiratory distress		1	0	0
	Hypoxia		1	0	0

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Reaction Count	Respiratory, thoracic and mediastinal disorders	Sputum increased	4	1	0
		Respiratory failure	1	0	0
		Respiratory disorder	5	0	1
		Choking	1	0	1
		Dysphonia	1	0	1
		Laryngospasm	7	1	7
		Stridor	2	0	1
		Epistaxis	1	0	0
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>51</b>	<b>6</b>	<b>22</b>
Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Angioedema	5	0	3
		Urticaria	5	1	0
		Dermatitis bullous	1	0	0
		Stevens-Johnson syndrome	1	0	0
		Toxic epidermal necrolysis	2	0	0
		Rash erythematous	8	0	0
		Skin exfoliation	2	0	1
		Photosensitivity reaction	3	0	1
		Pruritus	6	0	4
		Psoriasis	1	0	0
		Rash	14	0	6
		Rash macular	1	0	0
		Rash maculo-papular	14	0	2
		Rash morbilliform	1	0	0
		Melanodermia	1	0	0
		Acne	1	0	0
		Alopecia	1	0	0
		Cold sweat	2	0	1
		Hyperhidrosis	18	0	6
		Hair colour changes	1	0	1
		Seborrhoea	1	0	1
		Purpura	2	0	0
		<b>Skin and subcutaneous tissue disorders</b>	<b>91</b>	<b>1</b>	<b>26</b>
Surgical and medical procedures	Surgical and medical procedures	Therapy regimen changed	4	0	2

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Reaction Count	Surgical and medical procedures	<b>Surgical and medical procedures</b>	4	0	2
	Vascular disorders	Peripheral ischaemia	1	0	0
		Blood pressure fluctuation	2	0	0
		Hypotension	21	2	0
		Orthostatic hypotension	5	0	0
		Embolism arterial	1	0	0
		Vasodilatation	1	0	0
		Flushing	1	0	0
		Pallor	2	0	1
		Hypertension	8	0	3
		<b>Vascular disorders</b>	42	2	4
	<b>Reaction</b>		<b>1656</b>	<b>93</b>	<b>658</b>

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