

## **Medicine summary - Antipsychotics- risperidone**

		Case Group	Death Outcomes	Sole
Case Count		<b>1252</b>	<b>38</b>	<b>845</b>
Reaction Count	Blood and lymphatic system disorders	Iron deficiency anaemia	1	0
		Anaemia	7	0
		Pancytopenia	6	0
		Disseminated intravascular coagulation	1	1
		Thrombocytopenia	9	1
		Thrombocytosis	1	0
		Lymphadenopathy	2	0
		Eosinophilia	3	1
		Leukocytosis	8	0
		Leukopenia	7	1
		Lymphopenia	1	0
		Agranulocytosis	6	0
		Febrile neutropenia	1	0
		Neutropenia	21	14
		<b>Blood and lymphatic system disorders</b>	<b>74</b>	<b>3</b>
		Cardiac disorders	37	
		Atrioventricular block	2	0
		Arrhythmia	4	0
		Bradycardia	6	2
		Tachycardia	19	0
		Atrial fibrillation	2	1
		Supraventricular tachyarrhythmia	1	0
		Supraventricular tachycardia	5	2
		Cardiac arrest	5	3
		Ventricular fibrillation	1	0
		Palpitations	2	0
		Coronary artery disease	1	1
		Acute myocardial infarction	1	0
		Angina pectoris	1	1
		Myocardial infarction	7	2
		Cardiac failure	1	0
		Cardiac failure congestive	1	1
		Left ventricular failure	1	0

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

			Case Group	Death Outcomes	Sole
Reaction Count	Cardiac disorders	Cardiomyopathy	3	0	1
		Cardiomegaly	1	1	0
		Myocarditis	3	0	0
		Pericarditis	2	0	2
		<b>Cardiac disorders</b>	<b>69</b>	<b>10</b>	<b>40</b>
Reaction Count	Congenital, familial and genetic disorders	Congenital anomaly	1	0	1
		Deafness congenital	1	0	0
		Cleft palate	1	0	1
		Hip dysplasia	1	0	1
		Cerebral palsy	1	0	0
		Congenital neurological disorder	1	0	1
		Tourette's disorder	1	0	1
		<b>Congenital, familial and genetic disorders</b>	<b>7</b>	<b>0</b>	<b>5</b>
Reaction Count	Ear and labyrinth disorders	Deafness	1	0	1
		Hyperacusis	1	0	1
		<b>Ear and labyrinth disorders</b>	<b>2</b>	<b>0</b>	<b>2</b>
Reaction Count	Endocrine disorders	Cushingoid	1	0	1
		Hyperprolactinaemia	56	0	46
		Diabetes insipidus	1	0	0
		Inappropriate antidiuretic hormone secretion	3	0	1
		Goitre	1	0	0
		Hyperthyroidism	1	0	1
		Hypothyroidism	2	0	0
		<b>Endocrine disorders</b>	<b>65</b>	<b>0</b>	<b>49</b>
Reaction Count	Eye disorders	Lacration increased	1	0	1
		Eye oedema	1	0	1
		Eye pain	2	0	2
		Retinal disorder	1	0	0
		Periorbital oedema	6	0	4
		Glaucoma	1	0	1
		Conjunctivitis	1	0	0
		Eyelid oedema	1	0	1
		Eye pruritus	1	0	1

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Case Group	Death Outcomes	Sole
Reaction Count		
Eye disorders	Ocular hyperaemia	2 0 1
	Blepharospasm	5 0 5
	Eyelid ptosis	1 0 1
	Eye movement disorder	2 0 1
	Oculogyric crisis	14 0 6
	Photophobia	1 0 1
	Papilloedema	1 0 0
	Macular degeneration	1 0 0
	Retinal haemorrhage	1 0 0
	Retinopathy	1 0 1
	Blindness	2 0 2
	Visual acuity reduced	1 0 1
	Myopia	1 0 1
	Diplopia	1 0 0
	Vision blurred	14 0 12
	Visual impairment	5 0 4
	<b>Eye disorders</b>	<b>68 0 47</b>
Gastrointestinal disorders	Gingivitis	1 0 1
	Pancreatitis	3 0 2
	Gastrointestinal disorder	2 0 2
	Haematemesis	1 0 0
	Haematochezia	2 0 2
	Diarrhoea	3 0 3
	Constipation	9 0 6
	Gastroesophageal reflux disease	1 0 1
	Abdominal distension	4 0 4
	Flatulence	1 0 1
	Abdominal pain	7 0 1
	Abdominal pain upper	2 0 2
	Breath odour	1 0 1
	Dysphagia	20 1 13
	Faecal incontinence	5 0 3
	Nausea	13 0 9

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

		Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Vomiting	16	0
		Intestinal obstruction	2	0
		Duodenal ulcer haemorrhage	1	0
		Thrombosis mesenteric vessel	1	0
		Lip oedema	2	0
		Lip swelling	1	0
		Palatitis	1	0
		Oral mucosal eruption	1	0
		Stomatitis	1	0
		Retroperitoneal fibrosis	1	0
		Dry mouth	6	2
		Saliva altered	1	0
		Salivary hypersecretion	19	0
		Salivary gland enlargement	1	0
		Tongue disorder	1	0
		Swollen tongue	8	7
		Tongue oedema	6	5
		Tongue spasm	2	2
		<b>Gastrointestinal disorders</b>	<b>146</b>	<b>1</b>
General disorders and administration site conditions	General disorders and administration site conditions	Injection site mass	1	1
		Injection site pain	3	3
		Injection site reaction	2	2
		Hyperthermia malignant	2	1
		Hypothermia	4	3
		Hyperpyrexia	1	1
		Pyrexia	39	11
		Death	7	6
		Sudden death	3	3
		Asthenia	8	8
		Fatigue	18	13
		Malaise	12	6
		Abasia	3	3
		Gait disturbance	22	17

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Case Group	Death Outcomes	Sole	
Loss of control of legs	<b>1</b>	<b>0</b>	<b>1</b>
Condition aggravated	<b>7</b>	<b>0</b>	<b>6</b>
Exercise tolerance decreased	<b>1</b>	<b>0</b>	<b>1</b>
General physical health deterioration	<b>4</b>	<b>0</b>	<b>4</b>
Ill-defined disorder	<b>1</b>	<b>0</b>	<b>1</b>
Influenza like illness	<b>6</b>	<b>0</b>	<b>2</b>
Irritability	<b>2</b>	<b>0</b>	<b>2</b>
Swelling	<b>1</b>	<b>0</b>	<b>1</b>
Mucosal inflammation	<b>1</b>	<b>0</b>	<b>0</b>
Face oedema	<b>12</b>	<b>0</b>	<b>6</b>
Gravitational oedema	<b>3</b>	<b>0</b>	<b>0</b>
Oedema	<b>4</b>	<b>0</b>	<b>1</b>
Oedema peripheral	<b>11</b>	<b>0</b>	<b>11</b>
Chest pain	<b>6</b>	<b>0</b>	<b>4</b>
Pain	<b>3</b>	<b>0</b>	<b>3</b>
Chest discomfort	<b>2</b>	<b>0</b>	<b>2</b>
Chills	<b>3</b>	<b>0</b>	<b>2</b>
Feeling abnormal	<b>6</b>	<b>0</b>	<b>5</b>
Feeling hot	<b>1</b>	<b>0</b>	<b>1</b>
Feeling jittery	<b>2</b>	<b>0</b>	<b>0</b>
Hunger	<b>1</b>	<b>0</b>	<b>1</b>
Thirst	<b>3</b>	<b>0</b>	<b>2</b>
Drug interaction	<b>3</b>	<b>0</b>	<b>0</b>
Food interaction	<b>1</b>	<b>0</b>	<b>1</b>
Adverse event	<b>1</b>	<b>0</b>	<b>1</b>
Drug effect decreased	<b>1</b>	<b>0</b>	<b>0</b>
Drug ineffective	<b>19</b>	<b>1</b>	<b>16</b>
Therapeutic response decreased	<b>4</b>	<b>0</b>	<b>3</b>
Therapeutic response unexpected with drug substitution	<b>1</b>	<b>0</b>	<b>1</b>
Drug withdrawal syndrome	<b>4</b>	<b>0</b>	<b>3</b>
Drug withdrawal syndrome neonatal	<b>4</b>	<b>0</b>	<b>1</b>
Product taste abnormal	<b>1</b>	<b>0</b>	<b>1</b>

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	Product reconstitution issue	1	0	1
		Product shape issue	1	0	1
		Product quality issue	1	0	0
		Product substitution issue	1	0	1
		Product label confusion	1	0	1
		Exposure to contaminated device	2	0	2
		Injury associated with device	3	0	3
		Device leakage	1	0	1
		Device malfunction	5	0	5
		Syringe issue	1	0	1
		<b>General disorders and administration site conditions</b>	<b>262</b>	<b>12</b>	<b>177</b>
	Hepatobiliary disorders	Bile duct obstruction	1	0	0
		Gallbladder disorder	1	0	1
		Hepatitis cholestatic	1	0	1
		Jaundice	2	0	1
		Liver injury	1	0	0
		Hepatic function abnormal	29	1	13
		Hepatomegaly	1	0	0
		Hepatic steatosis	1	1	0
		Hepatitis	5	0	0
		<b>Hepatobiliary disorders</b>	<b>42</b>	<b>2</b>	<b>16</b>
	Immune system disorders	Hypersensitivity	4	1	4
		Anaphylactoid reaction	1	0	1
		<b>Immune system disorders</b>	<b>5</b>	<b>1</b>	<b>5</b>
	Infections and infestations	Cellulitis	1	0	1
		Appendicitis	1	0	1
		Mastitis	1	0	1
		Hepatic infection	1	0	1
		Abscess	2	0	0
		Infection	3	0	3
		Lower respiratory tract infection	1	0	1
		Pneumonia	4	2	1

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

			Case Group	Death Outcomes	Sole
Reaction Count	Infections and infestations	Sepsis	3	1	0
		Furuncle	1	0	1
		Subcutaneous abscess	1	0	1
		Pharyngitis	3	0	2
		Rhinitis	2	0	1
		Kidney infection	1	0	1
		Herpes zoster	1	0	1
		<b>Infections and infestations</b>	<b>26</b>	<b>3</b>	<b>16</b>
	Injury, poisoning and procedural complications	Spinal fracture	1	0	1
		Toxicity to various agents	4	1	0
		Drug exposure during pregnancy	19	0	11
		Subdural haematoma	1	0	1
		Muscle injury	1	0	1
		Tendon injury	1	0	1
		Fall	16	1	10
		Road traffic accident	1	0	1
		Drug administration error	2	0	2
		Drug dose omission	1	0	1
		Inappropriate schedule of drug administration	6	0	6
		Incorrect dose administered	6	1	3
		Incorrect drug administration duration	1	0	1
		Incorrect route of drug administration	1	0	1
		Underdose	1	0	1
		Medication error	4	0	3
		Accidental exposure	1	0	1
		Accidental overdose	1	0	0
		Intentional overdose	2	0	1
		Overdose	20	1	18
		<b>Injury, poisoning and procedural complications</b>	<b>90</b>	<b>4</b>	<b>64</b>
	Investigations	Ejection fraction decreased	1	0	0
		Electrocardiogram QT prolonged	11	0	5
		Electrocardiogram T wave inversion	2	0	2

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Reaction Count	Investigations	Case Group	Death Outcomes	Sole
	Electrocardiogram abnormal	2	0	1
	Heart rate abnormal	1	0	1
	Heart rate increased	1	0	1
	Heart rate irregular	2	0	2
	Blood pressure decreased	2	0	2
	Blood pressure increased	1	0	0
	Blood prolactin abnormal	1	0	1
	Blood prolactin increased	41	0	38
	Blood prolactin	1	0	1
	Blood testosterone decreased	1	0	1
	Blood testosterone increased	1	0	0
	Female sex hormone level abnormal	1	0	1
	Blood creatine phosphokinase increased	46	2	23
	Troponin increased	1	0	0
	Blood lactate dehydrogenase increased	1	0	1
	Prothrombin level increased	1	0	0
	Red blood cell sedimentation rate increased	2	0	0
	Platelet count decreased	1	0	1
	Neutrophil count decreased	1	0	1
	Alanine aminotransferase increased	2	0	0
	Aspartate aminotransferase increased	1	0	0
	Hepatic enzyme increased	3	0	1
	Liver function test abnormal	9	0	5
	Antiphospholipid antibodies positive	1	0	1
	Blood triglycerides increased	1	0	1
	Oxygen saturation decreased	1	0	0
	Blood glucose fluctuation	2	0	2
	Blood glucose increased	2	0	2
	Brain scan abnormal	1	0	1
	Electroencephalogram abnormal	1	0	1
	Apgar score low	1	0	1
	Body temperature fluctuation	1	0	1
	Weight decreased	10	0	5

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Reaction Count			Case Group	Death Outcomes	Sole
	Investigations	Weight increased	<b>61</b>	<b>0</b>	<b>49</b>
		Drug level above therapeutic	<b>1</b>	<b>0</b>	<b>0</b>
		Drug level increased	<b>2</b>	<b>1</b>	<b>0</b>
		<b>Investigations</b>	<b>222</b>	<b>3</b>	<b>152</b>
	Metabolism and nutrition disorders	Metabolic acidosis	<b>1</b>	<b>0</b>	<b>0</b>
		Decreased appetite	<b>6</b>	<b>0</b>	<b>4</b>
		Hypophagia	<b>1</b>	<b>0</b>	<b>0</b>
		Increased appetite	<b>8</b>	<b>0</b>	<b>7</b>
		Abnormal weight gain	<b>1</b>	<b>0</b>	<b>0</b>
		Feeding disorder	<b>1</b>	<b>0</b>	<b>1</b>
		Feeding disorder neonatal	<b>1</b>	<b>0</b>	<b>0</b>
		Obesity	<b>4</b>	<b>1</b>	<b>4</b>
		Weight fluctuation	<b>1</b>	<b>0</b>	<b>1</b>
		Hypercalcaemia	<b>1</b>	<b>1</b>	<b>0</b>
		Hypomagnesaemia	<b>1</b>	<b>1</b>	<b>0</b>
		Diabetic ketoacidosis	<b>1</b>	<b>0</b>	<b>0</b>
		Hypochloraemia	<b>1</b>	<b>1</b>	<b>0</b>
		Fluid intake reduced	<b>1</b>	<b>0</b>	<b>1</b>
		Polydipsia	<b>4</b>	<b>0</b>	<b>2</b>
		Hyperkalaemia	<b>1</b>	<b>0</b>	<b>1</b>
		Hypokalaemia	<b>2</b>	<b>0</b>	<b>1</b>
		Hypernatraemia	<b>2</b>	<b>0</b>	<b>1</b>
		Hyponatraemia	<b>15</b>	<b>1</b>	<b>6</b>
		Dehydration	<b>3</b>	<b>1</b>	<b>2</b>
		Diabetes mellitus	<b>11</b>	<b>0</b>	<b>8</b>
		Gestational diabetes	<b>3</b>	<b>0</b>	<b>2</b>
		Type 2 diabetes mellitus	<b>2</b>	<b>0</b>	<b>1</b>
		Glucose tolerance impaired	<b>1</b>	<b>0</b>	<b>1</b>
		Hyperglycaemia	<b>6</b>	<b>0</b>	<b>0</b>
		Hypoglycaemia	<b>2</b>	<b>0</b>	<b>0</b>
		Hypertriglyceridaemia	<b>1</b>	<b>0</b>	<b>1</b>
		Hyperproteinaemia	<b>1</b>	<b>0</b>	<b>1</b>
		Hipoproteinaemia	<b>2</b>	<b>0</b>	<b>1</b>

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Reaction Count			Case Group	Death Outcomes	Sole
Metabolism and nutrition disorders	Gout		1	0	0
	Vitamin B12 deficiency		1	0	1
	Hypovitaminosis		1	0	1
	<b>Metabolism and nutrition disorders</b>		<b>88</b>	<b>6</b>	<b>48</b>
Musculoskeletal and connective tissue disorders	Jaw disorder		1	0	1
	Systemic lupus erythematosus		1	0	1
	Synostosis		1	0	1
	Arthritis		1	0	0
	Arthralgia		2	0	1
	Joint stiffness		4	0	2
	Joint swelling		2	0	2
	Rheumatoid arthritis		1	0	1
	Myositis		1	0	1
	Myalgia		6	0	2
	Muscle disorder		2	0	2
	Muscle spasms		10	0	8
	Muscle tightness		1	0	1
	Muscle twitching		6	0	4
	Muscle rigidity		20	0	13
	Nuchal rigidity		1	0	1
	Torticollis		3	0	2
	Trismus		5	0	4
	Muscular weakness		3	0	3
	Myopathy		2	0	0
	Rhabdomyolysis		6	0	4
	Growth retardation		1	0	0
	Mastication disorder		1	0	0
	Mobility decreased		7	0	4
	Muscle contracture		3	0	1
	Musculoskeletal stiffness		25	0	14
	Posture abnormal		1	0	1
	Back pain		6	0	5
	Flank pain		1	0	0

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Reaction Count			Case Group	Death Outcomes	Sole
	Musculoskeletal and connective tissue disorders	Pain in extremity	<b>6</b>	<b>0</b>	<b>5</b>
		<b>Musculoskeletal and connective tissue disorders</b>	<b>130</b>	<b>0</b>	<b>84</b>
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	<b>4</b>	<b>0</b>	<b>3</b>
		Breast cancer female	<b>6</b>	<b>0</b>	<b>6</b>
		Breast cancer male	<b>1</b>	<b>0</b>	<b>1</b>
		Pituitary tumour benign	<b>6</b>	<b>0</b>	<b>6</b>
		Pituitary tumour	<b>1</b>	<b>0</b>	<b>0</b>
		Lip neoplasm	<b>1</b>	<b>0</b>	<b>0</b>
		Hairy cell leukaemia	<b>1</b>	<b>0</b>	<b>0</b>
		Non-Hodgkin's lymphoma	<b>1</b>	<b>0</b>	<b>0</b>
		Metastases to lung	<b>1</b>	<b>0</b>	<b>1</b>
		Squamous cell carcinoma	<b>1</b>	<b>0</b>	<b>0</b>
		Prolactinoma	<b>1</b>	<b>0</b>	<b>1</b>
		<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>24</b>	<b>0</b>	<b>18</b>
	Nervous system disorders	Intracranial aneurysm	<b>1</b>	<b>0</b>	<b>1</b>
		Cerebrovascular accident	<b>15</b>	<b>4</b>	<b>14</b>
		Cerebrovascular disorder	<b>3</b>	<b>0</b>	<b>2</b>
		Fahr's disease	<b>1</b>	<b>0</b>	<b>1</b>
		Transient ischaemic attack	<b>1</b>	<b>0</b>	<b>1</b>
		Cranial nerve disorder	<b>2</b>	<b>0</b>	<b>2</b>
		VIIth nerve paralysis	<b>2</b>	<b>0</b>	<b>2</b>
		Tongue paralysis	<b>3</b>	<b>0</b>	<b>3</b>
		Parosmia	<b>1</b>	<b>0</b>	<b>0</b>
		Encephalopathy	<b>1</b>	<b>0</b>	<b>0</b>
		Toxic encephalopathy	<b>1</b>	<b>0</b>	<b>0</b>
		Hyperammonaemic encephalopathy	<b>1</b>	<b>0</b>	<b>0</b>
		Headache	<b>18</b>	<b>0</b>	<b>11</b>
		Migraine	<b>3</b>	<b>0</b>	<b>3</b>
		Migraine with aura	<b>1</b>	<b>0</b>	<b>1</b>
		Benign intracranial hypertension	<b>1</b>	<b>0</b>	<b>1</b>
		Intracranial pressure increased	<b>2</b>	<b>0</b>	<b>1</b>
		Dementia	<b>3</b>	<b>0</b>	<b>2</b>

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	
	Amnesia	<b>10</b> <b>0</b> <b>9</b>
	Memory impairment	<b>1</b> <b>0</b> <b>1</b>
	Cognitive disorder	<b>3</b> <b>0</b> <b>2</b>
	Disturbance in attention	<b>2</b> <b>0</b> <b>0</b>
	Judgement impaired	<b>1</b> <b>0</b> <b>1</b>
	Mental impairment	<b>7</b> <b>1</b> <b>4</b>
	Choreoathetosis	<b>1</b> <b>0</b> <b>1</b>
	Akathisia	<b>29</b> <b>0</b> <b>18</b>
	Bradykinesia	<b>4</b> <b>0</b> <b>3</b>
	Dyskinesia	<b>29</b> <b>1</b> <b>20</b>
	Extrapyramidal disorder	<b>69</b> <b>0</b> <b>48</b>
	Hyperkinesia	<b>13</b> <b>0</b> <b>9</b>
	Hypokinesia	<b>7</b> <b>0</b> <b>6</b>
	Movement disorder	<b>2</b> <b>0</b> <b>1</b>
	Psychomotor hyperactivity	<b>1</b> <b>0</b> <b>0</b>
	Tardive dyskinesia	<b>47</b> <b>0</b> <b>37</b>
	Dystonia	<b>64</b> <b>0</b> <b>40</b>
	Opisthotonus	<b>3</b> <b>0</b> <b>2</b>
	Cogwheel rigidity	<b>13</b> <b>0</b> <b>7</b>
	Masked facies	<b>2</b> <b>0</b> <b>1</b>
	Parkinsonian gait	<b>4</b> <b>0</b> <b>3</b>
	Parkinsonism	<b>21</b> <b>1</b> <b>13</b>
	Tremor	<b>33</b> <b>0</b> <b>16</b>
	Hyperreflexia	<b>2</b> <b>0</b> <b>0</b>
	Hyporeflexia	<b>1</b> <b>0</b> <b>0</b>
	Ataxia	<b>6</b> <b>0</b> <b>4</b>
	Balance disorder	<b>5</b> <b>0</b> <b>5</b>
	Coordination abnormal	<b>2</b> <b>0</b> <b>1</b>
	Coma	<b>3</b> <b>0</b> <b>0</b>
	Diabetic hyperosmolar coma	<b>1</b> <b>0</b> <b>0</b>
	Aphasia	<b>3</b> <b>0</b> <b>2</b>
	Consciousness fluctuating	<b>11</b> <b>1</b> <b>8</b>
	Depressed level of consciousness	<b>3</b> <b>1</b> <b>2</b>

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Case Group	Death Outcomes	Sole	
Lethargy	<b>6</b>	<b>0</b>	<b>4</b>
Loss of consciousness	<b>1</b>	<b>0</b>	<b>1</b>
Sedation	<b>11</b>	<b>1</b>	<b>6</b>
Somnolence	<b>25</b>	<b>0</b>	<b>17</b>
Stupor	<b>2</b>	<b>1</b>	<b>1</b>
Syncope	<b>11</b>	<b>1</b>	<b>10</b>
Nervous system disorder	<b>1</b>	<b>0</b>	<b>1</b>
Clonus	<b>2</b>	<b>0</b>	<b>0</b>
Dizziness	<b>29</b>	<b>0</b>	<b>17</b>
Drooling	<b>7</b>	<b>0</b>	<b>6</b>
Meningism	<b>1</b>	<b>0</b>	<b>1</b>
Myoclonus	<b>3</b>	<b>0</b>	<b>1</b>
Crying	<b>1</b>	<b>0</b>	<b>1</b>
Paraesthesia	<b>5</b>	<b>0</b>	<b>5</b>
Ageusia	<b>1</b>	<b>0</b>	<b>1</b>
Hypoesthesia	<b>5</b>	<b>0</b>	<b>4</b>
Restless legs syndrome	<b>3</b>	<b>0</b>	<b>2</b>
Sensory disturbance	<b>2</b>	<b>0</b>	<b>2</b>
Aphonia	<b>1</b>	<b>0</b>	<b>1</b>
Dysarthria	<b>15</b>	<b>0</b>	<b>8</b>
Incoherent	<b>1</b>	<b>0</b>	<b>0</b>
Speech disorder	<b>8</b>	<b>0</b>	<b>5</b>
Drop attacks	<b>2</b>	<b>0</b>	<b>1</b>
Hypertonia	<b>32</b>	<b>2</b>	<b>13</b>
Hypotonia	<b>2</b>	<b>0</b>	<b>2</b>
Neuroleptic malignant syndrome	<b>66</b>	<b>2</b>	<b>33</b>
Serotonin syndrome	<b>3</b>	<b>0</b>	<b>1</b>
Muscle contractions involuntary	<b>1</b>	<b>0</b>	<b>1</b>
Nerve compression	<b>1</b>	<b>0</b>	<b>0</b>
Neuropathy peripheral	<b>3</b>	<b>0</b>	<b>0</b>
Grand mal convulsion	<b>7</b>	<b>0</b>	<b>4</b>
Simple partial seizures	<b>1</b>	<b>0</b>	<b>1</b>
Convulsion	<b>36</b>	<b>2</b>	<b>21</b>

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Partial seizures with secondary generalisation	1	0	1
		Sleep phase rhythm disturbance	1	0	0
		Hypersomnia	2	0	2
		Poor quality sleep	1	0	1
		Brain injury	2	1	1
		<b>Nervous system disorders</b>	<b>765</b>	<b>19</b>	<b>485</b>
	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	5	0	3
		Foetal distress syndrome	2	0	2
		Foetal hypokinesia	1	0	0
		Foetal growth restriction	2	0	0
		Premature labour	2	0	0
		Abnormal labour	1	0	0
		Pre-eclampsia	1	0	0
		Gestational hypertension	1	0	1
		Premature baby	4	0	0
		Small for dates baby	2	0	0
		Weight decrease neonatal	1	0	0
		Neonatal disorder	1	0	0
		Postpartum haemorrhage	1	0	1
		<b>Pregnancy, puerperium and perinatal conditions</b>	<b>24</b>	<b>0</b>	<b>7</b>
	Psychiatric disorders	Agitation	30	1	18
		Anxiety	19	0	14
		Nervousness	2	0	1
		Neurosis	1	0	1
		Obsessive-compulsive disorder	2	0	2
		Catatonia	9	0	5
		Restlessness	9	0	7
		Bruxism	1	0	0
		Tic	2	0	2
		Mutism	1	0	0
		Dysphemia	2	0	1
		Confusional state	34	1	18

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Case Group	Death Outcomes	Sole	
Disorientation	<b>3</b>	<b>0</b>	<b>2</b>
Delirium	<b>11</b>	<b>1</b>	<b>5</b>
Depression	<b>7</b>	<b>0</b>	<b>5</b>
Depressed mood	<b>5</b>	<b>0</b>	<b>2</b>
Depressive symptom	<b>1</b>	<b>0</b>	<b>0</b>
Tearfulness	<b>1</b>	<b>0</b>	<b>1</b>
Depersonalisation	<b>3</b>	<b>0</b>	<b>2</b>
Delusion	<b>8</b>	<b>0</b>	<b>8</b>
Hallucination	<b>13</b>	<b>0</b>	<b>9</b>
Hallucination, auditory	<b>3</b>	<b>1</b>	<b>2</b>
Hallucination, visual	<b>1</b>	<b>0</b>	<b>1</b>
Thinking abnormal	<b>8</b>	<b>0</b>	<b>5</b>
Eating disorder	<b>1</b>	<b>0</b>	<b>1</b>
Hypomania	<b>1</b>	<b>0</b>	<b>0</b>
Mania	<b>3</b>	<b>0</b>	<b>1</b>
Affect lability	<b>2</b>	<b>0</b>	<b>1</b>
Flat affect	<b>4</b>	<b>0</b>	<b>4</b>
Blunted affect	<b>2</b>	<b>0</b>	<b>2</b>
Anger	<b>3</b>	<b>0</b>	<b>2</b>
Dysphoria	<b>1</b>	<b>0</b>	<b>1</b>
Elevated mood	<b>1</b>	<b>0</b>	<b>0</b>
Emotional distress	<b>2</b>	<b>0</b>	<b>1</b>
Euphoric mood	<b>1</b>	<b>0</b>	<b>1</b>
Frustration	<b>1</b>	<b>0</b>	<b>0</b>
Mood swings	<b>2</b>	<b>0</b>	<b>2</b>
Apathy	<b>2</b>	<b>0</b>	<b>2</b>
Aggression	<b>26</b>	<b>1</b>	<b>15</b>
Disinhibition	<b>1</b>	<b>0</b>	<b>0</b>
Homicidal ideation	<b>5</b>	<b>0</b>	<b>1</b>
Paranoia	<b>2</b>	<b>0</b>	<b>2</b>
Personality change	<b>1</b>	<b>0</b>	<b>1</b>
Social avoidant behaviour	<b>1</b>	<b>0</b>	<b>1</b>
Violence-related symptom	<b>1</b>	<b>0</b>	<b>0</b>

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Reaction Count			Case Group	Death Outcomes	Sole
Psychiatric disorders	Abnormal behaviour		7	2	3
	Staring		1	0	0
	Psychiatric symptom		2	0	1
	Mental disorder		1	0	0
	Alcohol abuse		1	0	1
	Intentional drug misuse		1	0	1
	Withdrawal syndrome		6	0	6
	Psychotic disorder		12	0	6
	Schizophrenia		3	0	2
	Anorgasmia		2	0	2
	Libido decreased		2	0	2
	Loss of libido		2	0	2
	Insomnia		22	0	14
	Abnormal dreams		1	0	1
	Nightmare		6	0	1
	Somnambulism		2	0	0
	Sleep disorder		2	0	1
	Completed suicide		5	5	3
	Intentional self-injury		1	0	0
	Self injurious behaviour		3	0	2
	Suicidal ideation		22	0	11
	Suicide attempt		9	0	4
	<b>Psychiatric disorders</b>		<b>352</b>	<b>12</b>	<b>212</b>
Renal and urinary disorders	Tubulointerstitial nephritis		1	0	0
	Renal failure		1	0	0
	Renal failure acute		4	0	1
	Renal impairment		8	1	5
	Dysuria		2	0	2
	Incontinence		2	0	1
	Micturition disorder		1	0	0
	Pollakiuria		2	0	1
	Urinary incontinence		13	0	8
	Urinary retention		3	0	2

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Reaction Count			Case Group	Death Outcomes	Sole
	Renal and urinary disorders	Glycosuria	1	0	1
		Haematuria	2	0	2
		Ketonuria	1	0	1
		Myoglobinuria	1	0	0
		Polyuria	2	0	1
		Nephrolithiasis	1	0	1
		<b>Renal and urinary disorders</b>	<b>45</b>	<b>1</b>	<b>26</b>
	Reproductive system and breast disorders	Breast cyst	1	0	1
		Breast enlargement	4	0	2
		Breast mass	2	0	2
		Gynaecomastia	10	0	9
		Breast discharge	1	0	1
		Breast engorgement	1	0	1
		Breast pain	6	0	4
		Breast tenderness	1	0	1
		Nipple exudate bloody	1	0	1
		Nipple pain	1	0	1
		Galactorrhoea	41	0	33
		Lactation disorder	3	0	3
		Menstrual disorder	4	0	4
		Menstruation irregular	3	0	2
		Metrorrhagia	1	0	1
		Amenorrhoea	31	0	27
		Menorrhagia	1	0	1
		Polycystic ovaries	1	0	0
		Penile swelling	1	0	1
		Genital ulceration	1	0	0
		Oedema genital	1	0	1
		Ejaculation disorder	1	0	0
		Ejaculation failure	8	0	8
		Erectile dysfunction	8	0	7
		Painful erection	1	0	1
		Priapism	11	0	11

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

			Case Group	Death Outcomes	Sole
Reaction Count	Reproductive system and breast disorders	Infertility	1	0	1
		Sexual dysfunction	5	0	5
		Testicular disorder	2	0	1
		Testicular pain	1	0	1
		<b>Reproductive system and breast disorders</b>	<b>154</b>	<b>0</b>	<b>131</b>
Reaction Count	Respiratory, thoracic and mediastinal disorders	Asthma	1	1	1
		Bronchospasm	2	0	1
		Wheezing	2	0	2
		Pneumonia aspiration	2	0	0
		Pulmonary oedema	2	2	1
		Neonatal respiratory distress syndrome	1	0	1
		Pulmonary embolism	4	0	4
		Apnoea	1	0	0
		Dyspnoea	32	1	21
		Dyspnoea exertional	1	0	1
		Hyperventilation	1	0	1
		Hypoventilation	2	0	1
		Respiratory arrest	1	0	0
		Respiratory depression	4	0	1
		Respiratory distress	3	0	1
		Tachypnoea	1	0	1
		Asphyxia	1	1	0
		Haemoptysis	1	0	1
		Respiratory failure	2	2	1
		Respiratory disorder	1	0	1
		Choking	4	0	3
		Dry throat	1	0	1
		Oropharyngeal pain	2	0	1
		Rhinorrhoea	1	0	1
		Throat tightness	2	0	2
		Stridor	1	0	1
		Nasal congestion	1	0	0
		Epistaxis	5	0	5

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

Reaction Count			Case Group	Death Outcomes	Sole
	Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	1	0	1
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>83</b>	<b>7</b>	<b>55</b>
	Skin and subcutaneous tissue disorders	Angioedema	7	0	5
		Urticaria	12	0	9
		Lichenoid keratosis	1	0	1
		Skin striae	1	0	1
		Dermatitis bullous	1	0	1
		Erythema multiforme	1	0	0
		Pemphigoid	1	0	1
		Dry skin	2	0	2
		Skin discolouration	1	0	1
		Skin disorder	2	0	0
		Skin odour abnormal	2	0	0
		Swelling face	5	0	4
		Dermatitis	2	0	1
		Eczema	1	0	1
		Seborrhoeic dermatitis	1	0	0
		Erythema	5	0	2
		Rash erythematous	4	0	4
		Skin exfoliation	6	0	3
		Rash papular	1	0	1
		Photosensitivity reaction	1	0	0
		Pruritus	17	0	12
		Rash pruritic	3	0	0
		Psoriasis	2	0	1
		Rash	27	0	18
		Rash generalised	2	0	2
		Rash macular	2	0	0
		Rash maculo-papular	5	0	3
		Skin hyperpigmentation	1	0	0
		Skin hypopigmentation	1	0	1
		Alopecia	5	0	4

 [Outcome Description](#)

 [\(Causality possible,Causality probable,Causality certain\)](#)

 [Suspect Type](#)

 [Suspect Code](#)

 [Case Group](#)

 [GM](#)

 [Risperidone](#)

## **Medicine summary - Antipsychotics- risperidone**

			Case Group	Death Outcomes	Sole
Reaction Count	Skin and subcutaneous tissue disorders	Cold sweat	1	0	0
		Hyperhidrosis	9	0	4
		Hirsutism	1	0	0
		Hypertrichosis	1	0	0
		Hair texture abnormal	1	0	0
		Seborrhoea	1	0	1
		Purpura	2	0	0
		Livedo reticularis	1	0	1
		<b>Skin and subcutaneous tissue disorders</b>	<b>139</b>	<b>0</b>	<b>84</b>
Social circumstances	Social circumstances	Activities of daily living impaired	1	0	1
		Bedridden	1	0	1
		Treatment noncompliance	4	0	1
		<b>Social circumstances</b>	<b>6</b>	<b>0</b>	<b>3</b>
Surgical and medical procedures	Surgical and medical procedures	Hospitalisation	1	0	1
		Off label use	2	0	2
		Therapy regimen changed	19	0	10
		Self-medication	1	0	0
		<b>Surgical and medical procedures</b>	<b>23</b>	<b>0</b>	<b>13</b>
Vascular disorders	Vascular disorders	Infarction	1	0	1
		Blood pressure fluctuation	1	0	0
		Circulatory collapse	9	1	7
		Hypotension	22	0	11
		Orthostatic hypotension	15	1	12
		Thrombosis	2	1	2
		Deep vein thrombosis	4	0	4
		Flushing	6	0	3
		Hot flush	2	0	2
		Pallor	2	0	1
		Hypertension	4	0	2
		<b>Vascular disorders</b>	<b>68</b>	<b>3</b>	<b>45</b>
<b>Reaction</b>			<b>2979</b>	<b>87</b>	<b>1915</b>

🚫 Rows are suppressed based on zeros and empty cells for Case Group

👉 [Outcome Description](#)

👉 [\(Causality possible,Causality probable,Causality certain\)](#)

👉 [Suspect Type](#)

👉 [Suspect Code](#)

👉 [Case Group](#)

👉 [GM](#)

👉 [Risperidone](#)