PACKAGE INSERT

SCHEDULING STATUS

Schedule 5

PROPRIETARY NAME AND DOSAGE FORM

RISPERDAL® 0,5 mg tablets.

RISPERDAL®1 mg tablets.

RISPERDAL® 2 mg tablets.

RISPERDAL® 3 mg tablets.

RISPERDAL® 4 mg tablets.

COMPOSITION

Each tablet contains risperidone 0,5 mg.

Each tablet contains risperidone 1 mg.

Each tablet contains risperidone 2 mg.

Each tablet contains risperidone 3 mg.

Each tablet contains risperidone 4 mg.

The oral tablets also contain: lactose, maize starch, cellulose, hypromellose, magnesium stearate, silicon dioxide, sodium laurylsulfate and propylene glycol.

The 0,5 milligram tablet also contains talc, titanium dioxide and red ferric oxide.

The 2 milligram tablet also contains talc, titanium dioxide and orange yellow S.

The 3 milligram tablet also contains talc, titanium dioxide and quinoline yellow.

The 4 milligram tablet also contains talc, titanium dioxide, quinoline yellow & indigotin lake.

Contains Sugar.

PHARMACOLOGICAL CLASSIFICATION

A.2.6.5 Central nervous system depressants. Miscellaneous structures.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

Risperidone is an antipsychotic of the benzisoxazol derivatives. It is a selective monoaminergic antagonist. Risperidone has affinity for serotonin-5-HT_2, dopamine-D_2, H_1-histamine, α_1- and α_2-adrenergic receptors. Risperidone has no affinity for cholinergic receptors. It is a dopamine D_2-antagonist.

Pharmacokinetic properties:

Risperidone is completely absorbed after oral administration. Peak plasma concentrations are attained within 1 to 2 hours. Food does not affect the absorption of risperidone.

Risperidone is metabolised by cytochrome CYP 2D6 to 9-hydroxy-risperidone, which has a similar pharmacological activity to risperidone. Risperidone and 9-hydroxy-risperidone form the active antipsychotic fraction.

After oral administration to psychotic patients, risperidone's half-life is about 3 hours. The elimination half-life of 9-hydroxy-risperidone and the active antipsychotic fraction is 24 hours.

Following 6 mg or 8 mg once daily, peak levels of the active moiety were about 30 % higher and trough levels about 30 % lower than the peaks and troughs following 3 and 4 mg twice daily.
Steady state is reached within 1 day for risperidone in most patients and 4-5 days for 9-hydroxy-risperidone.

Risperidone plasma concentration is dose-proportional within the therapeutic dose-range. Risperidone is bound to albumin and alpha$_1$-acid glycoprotein. Plasma protein binding of

risperidone is 88 % and 77 % for 9-hydroxy-risperidone. One week after administration, 70 % of the dose is excreted in the urine and 14 % in the faeces. In urine, risperidone and 9-hydroxy-risperidone represent 35 - 45 % of the dose.

A single dose study showed higher active plasma concentrations and a reduced clearance of the active antipsychotic fraction by 30 % in the elderly and 50 % in patients with moderate renal insufficiency. In patients with severe renal insufficiency the clearance was one third that of normal. The plasma concentrations of risperidone were normal in patients with liver insufficiency, but the mean free fraction of risperidone in plasma was increased by about 35 %.

The pharmacokinetics of risperidone, 9-hydroxy-risperidone and the active moiety in children are similar to those in adults.

INDICATIONS

RISPERDAL is indicated for the treatment of:

Acute and chronic schizophrenic psychoses and related psychosis in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness) and/or the negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERDAL also alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. In patients who have shown an initial treatment response, RISPERDAL is also effective in maintaining the clinical improvement.

Mania in bipolar disorder. These episodes are characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviours.

Conduct and other disruptive behaviour disorders in children (aged 5 – 12 years), with subaverage intellectual functioning or mental retardation in whom destructive behaviours (e.g. aggression, impulsivity and self-injurious behaviours) are prominent.

CONTRAINDICATIONS

RISPERDAL is contraindicated in patients with known hypersensitivity to risperidone or to any of the components of the medicine.

Conduct and other disruptive behaviour disorders in children: RISPERDAL is contraindicated in children under 5 years of age as efficacy and safety in these children have not been demonstrated.

Parkinson's disease and Lewy Body Dementia (see WARNINGS AND SPECIAL PRECAUTIONS).

WARNINGS AND SPECIAL PRECAUTIONS

Elderly Patients with Dementia

Overall Mortality

Elderly patients with dementia treated with atypical antipsychotic medicines have an increased mortality compared to placebo in a meta-analysis of 17 controlled trials of atypical antipsychotic medicines, including RISPERDAL. In placebo-controlled trials with oral RISPERDAL in this population, the incidence of mortality was 4,0 % for RISPERDAL-treated patients compared to 3,1 % for placebo-treated patients. The mean age (range) of patients who died was 86 years (range 67-100).

Concomitant use with furosemide

In RISPERDAL placebo-controlled trials in elderly patients with dementia, a higher incidence of mortality was observed in patients treated with furosemide and RISPERDAL (7,3 %; mean age 89 years, range 75-97) when compared to patients treated with RISPERDAL alone (3,1 %; mean age 84 years, range 70-96) or furosemide alone (4,1 %; mean age 80 years, range 67-90). The increase in mortality in patients treated with furosemide plus RISPERDAL was observed in two of the four clinical trials.

No pathophysiological mechanism has been identified to explain this finding, and no consistent pattern for cause of death observed. Nevertheless, caution should be exercised and the risks and benefits of this combination should be considered prior to the decision to use. There was no increased incidence of mortality among patients taking other diuretics as concomitant medication with RISPERDAL. Irrespective of treatment, dehydration was an overall risk factor for mortality and should therefore be carefully avoided in elderly patients with dementia.

Cerebrovascular Adverse Events (CAE)

In placebo-controlled clinical trials in elderly patients with dementia, there was a higher incidence of cerebrovascular adverse events (cerebrovascular accidents and transient ischaemic attacks), including fatalities, in patients treated with RISPERDAL compared to patients receiving placebo (mean age 85 years; range 73-97 years).

Orthostatic Hypotension

Due to the alpha-blocking activity of RISPERDAL, (orthostatic) hypotension can occur, especially during the initial dose-titration period. RISPERDAL should be used with caution in patients with known cardiovascular disease, and the dosage should be gradually titrated as recommended. A dose reduction should be considered if hypotension occurs.

Leucopaenia, Neutropaenia, and Agranulocytosis

Events of leucopaenia, neutropaenia and agranulocytosis have been reported with RISPERDAL. Agranulocytosis has been reported during post-marketing surveillance.

Patients with a history of a clinically significant low white blood cell count (WBC) or a medicine-induced leucopaenia/neutropaenia should be monitored during therapy and discontinuation of RISPERDAL should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors.

Patients with clinically significant neutropaenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropaenia (absolute neutrophil count < 1 X 10^9/L) should discontinue RISPERDAL and have their WBC followed until recovery.

Venous thromboembolism

Cases of venous thromboembolism (VTE) have been reported with RISPERDAL. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with RISPERDAL and preventive measures undertaken.

Tardive Dyskinesia/Extrapyramidal Symptoms (TD/EPS)

RISPERDAL has been associated with the induction of tardive dyskinesia (TD) characterised by potentially irreversible rhythmical involuntary movements, predominantly of the tongue and/or face. It has been reported that the occurrence of extrapyramidal symptoms is a risk factor for the development of tardive dyskinesia. TD appears to be most prominent in the elderly especially elderly females. If signs and symptoms of tardive dyskinesia appear, the discontinuation of RISPERDAL should be considered.

Neuroleptic Malignant Syndrome (NMS)

Neuroleptic Malignant Syndrome, a potentially fatal symptom complex, characterised by hyperthermia, muscle rigidity, autonomic instability, altered consciousness and elevated serum creatine phosphokinase levels has been reported to occur in association with RISPERDAL. Additional signs may include elevated creatine phosphokinase levels, myoglobinuria (rhabdomyolysis) and acute renal failure. In this event, RISPERDAL, should be discontinued.

Parkinson's disease/Lewy Body dementia and NMS

Patients with Parkinson's disease or Dementia with Lewy Bodies (DLB) have an increased risk of Neuroleptic Malignant Syndrome (NMS) as well as having an increased sensitivity to antipsychotic medications (see CONTRAINDICATIONS). Manifestation of this increased sensitivity can include confusion, obtundation and postural instability with frequent falls, in addition to extrapyramidal symptoms. In addition, in clinical trials, elderly patients have a higher mortality than placebo treated elderly patients. (see CONTRAINDICATIONS).

Hyperglycaemia and diabetes mellitus

Hyperglycaemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with RISPERDAL.

Patients with an established diagnosis of diabetes mellitus who are starting on RISPERDAL should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g. obesity, family history of diabetes) who are starting treatment with RISPERDAL should be monitored for symptoms of hyperglycaemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycaemia during treatment with RISPERDAL should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved when RISPERDAL were discontinued; however, some

patients required continuation of anti-diabetic treatment despite discontinuation of RISPERDAL.

Weight gain

Significant weight gain has been reported. Monitoring weight gain is advisable when RISPERDAL is being used. Patients may be advised to refrain from excessive eating in view of the possibility of weight gain.

QT Interval

Caution should be exercised when RISPERDAL is prescribed in patients with a history of cardiac dysrhythmias, in patients with congenital long QT syndrome, and in concomitant use with medicines known to prolong the QT interval.

Priapism

Medicines with alpha-adrenergic blocking effects have been reported to induce priapism. Priapism has been reported with RISPERDAL during postmarketing surveillance (see SIDE EFFECTS).

Body Temperature Regulation

Disruption of the body's ability to reduce core body temperature may occur. Appropriate care is advised when prescribing RISPERDAL to patients who will be experiencing conditions which may contribute to an elevation in core body temperature, e.g. exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.

Antiemetic Effect

An antiemetic effect was observed in preclinical studies with risperidone. This effect, if it occurs in humans, may mask the signs and symptoms of overdosage with certain

medicines or of conditions such as intestinal obstruction, Reye's syndrome, and brain tumour.

Intraoperative Floppy Iris Syndrome

Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract surgery in patients treated with medicines with alpha1a-adrenergic antagonist effect, including RISPERDAL.

IFIS may increase the risk of eye complications during and after the operation. Current or past use of RISPERDAL should be made known to the ophthalmic surgeon in advance of surgery. The potential benefit of stopping RISPERDAL prior to cataract surgery has not been established and must be weighed against the risk of stopping RISPERDAL therapy.

Seizures

RISPERDAL should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold.

Ability to drive or use machinery

RISPERDAL may impair mental alertness. Patients should therefore be advised not to drive or operate machinery until their individual susceptibility is known.

Galactose intolerance

RISPERDAL contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take RISPERDAL.

INTERACTIONS

There is increased mortality in elderly patients with dementia concomitantly receiving furosemide and RISPERDAL (see WARNINGS AND SPECIAL PRECAUTIONS).

The risk of using RISPERDAL in combination with other medicines has not been systematically evaluated. Given the primary CNS depressive effects of RISPERDAL, it should be used with caution in combination with alcohol and other centrally acting medicines.

RISPERDAL may antagonise the effect of levodopa and other dopamine agonists.

Clinically significant hypotension has been observed postmarketing with concomitant use of RISPERDAL and antihypertensive treatment (see WARNINGS AND SPECIAL PRECAUTIONS).

Caution is advised when prescribing RISPERDAL with medicines known to prolong the QT interval (See WARNINGS AND SPECIAL PRECAUTIONS).

Carbamazepine has been shown to decrease the plasma levels of the active antipsychotic fraction of risperidone. Similar effects may be observed with other CYP3A4 hepatic enzyme inducers. On discontinuation of carbamazepine or other hepatic enzyme inducers, the dosage of RISPERDAL should be re-evaluated and, if necessary, decreased.

Fluoxetine and paroxetine, CYP 2D6 inhibitors, increase the plasma concentration of risperidone but less so of the active anti-psychotic fraction. When concomitant fluoxetine or paroxetine is initiated or discontinued, the dosing of RISPERDAL should be re-evaluated.

Venlafaxine administered under steady-state conditions at 150 mg/day inhibited the CYP2D6-mediated metabolism of risperidone (administered as a single 1 mg oral dose) to its active metabolite, 9-hydroxyrisperidone, resulting in an approximate 32 % increase in risperidone

AUC. However, venlafaxine coadministration did not significantly alter the pharmacokinetic profile of the total active antipsychotic fraction.

Topiramate: modestly reduced the bioavailability of risperidone, but not that of the active antipsychotic fraction. Therefore, this interaction is unlikely to be of clinical significance.

Phenothiazines, tricyclic antidepressants and some beta-blockers may increase the plasma concentration of risperidone but not that of the active antipsychotic fraction.

Amitriptyline does not affect the pharmacokinetics of risperidone or the active antipsychotic fraction. Cimetidine and ranitidine increased the bioavailability of risperidone, but only marginally that of the active antipsychotic fraction.

Erythromycin, a CYP 3A4 inhibitor, does not change the pharmacokinetics of risperidone and the active antipsychotic fraction.

The cholinesterase inhibitors, galantamine and donepezil, do not show a clinically relevant effect on the pharmacokinetics of risperidone and the active antipsychotic fraction.

When RISPERDAL is taken together with other highly protein-bound medicines (e.g. diazepam, warfarin, digoxin, imipramine and propranolol), there is no clinically relevant displacement of either agent from the plasma proteins.

RISPERDAL does not show a clinically relevant effect on the pharmacokinetics of lithium, valproate, digoxin or topiramate.

Food does not affect the absorption of RISPERDAL.

PREGNANCY AND LACTATION

The safety of RISPERDAL in pregnancy and lactating women has not been established. Although, in experimental animals, risperidone did not show direct reproductive toxicity, some indirect, prolactin- and CNS-mediated effects were observed. No teratogenic effect of risperidone was noted in any study.

Neonates exposed to antipsychotic medicines (including RISPERDAL) during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms that may vary in severity following delivery. These symptoms in the neonates may include agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder.

Therefore, RISPERDAL should only be used during pregnancy if the benefits outweigh the risks.

Lactation: In animal studies risperidone and 9-hydroxy- risperidone are excreted in the milk. It has been demonstrated that risperidone and 9-hydroxy-risperidone are also excreted in human breast milk. Therefore, women receiving RISPERDAL should not breastfeed.

DOSAGE AND DIRECTIONS FOR USE

- **Schizophrenia**

Switching from other antipsychotics to RISPERDAL:

When medically appropriate, gradual discontinuation of the previous treatment, while RISPERDAL therapy is initiated, is recommended. Also if medically appropriate, when switching patients from depot antipsychotics, initiate RISPERDAL therapy in place of the next scheduled injection. The need for continuing existing anti-Parkinson medications should be re-evaluated periodically.

Adults:

RISPERDAL may be given once or twice daily**.**

Patients should start with 2 mg/day RISPERDAL. The dosage may be increased on the second day to 4 mg/day. From then on, the dosage can be maintained unchanged, or further individualised, if needed. Most patients will benefit from daily doses of between 4 mg/day and 8 mg/day. Doses above 6 mg/day (when administered twice daily) were associated with more extrapyramidal symptoms and other adverse effects and are not generally recommended. In some patients, particularly with first episode acute psychosis, a slower titration phase and a lower starting and maintenance dose may be appropriate.

Doses above 10 mg/day have not been shown to be superior in efficacy to lower doses and may cause an increased incidence of side-effects such as extrapyramidal symptoms. Dosages above 10 mg/day should only be considered if the benefits outweigh the risk. The maximum total daily dose is 16 mg/day.

A benzodiazepine may be added to RISPERDAL if additional sedation is required.

Elderly patients and patients with renal and hepatic impairment.

A starting dose of 0,5 mg twice daily is recommended. This dosage can be individually adjusted with 0,5 mg twice daily increments to 1 - 2 mg twice daily.

Children:

Not for children under 15 years as efficacy and safety in children under the age of 15 years have not been demonstrated in schizophrenia.

- **Mania in bipolar disorders**

RISPERDAL should be administered on a once daily schedule, starting with 2 or 3 mg. Dosage adjustments, if indicated, should occur at intervals of not less than 24 hours and in dosage increments of 1 mg per day. Efficacy was demonstrated in flexible doses over a range of 1 to 6 mg per day.
The continued use of RISPERDAL must be evaluated and justified on an ongoing basis.
Experience is lacking in bipolar mania in children and adolescents less than 18 years of age.

- **Conduct and other Disruptive Behaviour Disorders (DBD) in children 5 - 12 years of age**

Patients < 50 kg:

A starting dose of 0,01 mg/kg once daily is recommended. This dosage can be individually adjusted by increments of 0,01 mg/kg once daily not more frequently than every other day, if needed. The recommended maintenance dose is 0,02 – 0,04 mg/kg once daily. The mean dose is 0,03 mg/kg once daily.

The continued use of RISPERDAL must be evaluated and justified on an ongoing basis.
Experience is lacking in children aged less than 5 years.

Renal and liver impairment

Patients with renal impairment have less ability to eliminate the active antipsychotic fraction than normal adults. Patients with impaired hepatic function have increases in plasma concentration of the free fraction of risperidone.

Irrespective of the indication, starting and consecutive dosing should be halved, and dose titration should be slower for patients with renal or hepatic impairment.
RISPERDAL should be used with caution in these groups of patients.

SIDE EFFECTS

Adverse drug reactions (ADRs) reported during clinical trials:

ADRs are listed below by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000)

Investigations:

Common: Increased blood prolactin , increased weight

Uncommon: Abnormal electrocardiogram, increased blood glucose, increased transaminases, decreased white blood cell count, increased body temperature, increased eosinophil count, decreased haemoglobin, increased blood creatine phosphokinase

Rare: Decreased body temperature

Cardiac disorders:

Common: Tachycardia

Uncommon: Atrioventricular block, bundle branch block, sinus bradycardia, palpitations

Blood and lymphatic system disorders:

Uncommon: Anaemia, neutropaenia

Rare: Granulocytopaenia

Nervous system disorders

Very common: Parkinsonism , headache

Common: Akathisia , dizziness, tremor , dystonia , somnolence, sedation, lethargy, dyskinesia

Uncommon: Unresponsive to stimuli, loss of consciousness, syncope, depressed level of consciousness, cerebrovascular accident, transient ischaemic attack, dysarthria, disturbance in attention, hypersomnia**,** postural dizziness, balance disorder,

tardive dyskinesia, speech disorder, coordination abnormal, hypoaesthesia, head titubation

Rare: Neuroleptic malignant syndrome, diabetic coma, cerebrovascular disorder, cerebral ischaemia, movement disorder

Eye disorder

Common: Blurred vision

Uncommon: Conjunctivitis, ocular hyperaemia, eye discharge, eye swelling, dry eye, increased lacrimation, photophobia

Rare: Reduced visual acuity, eye rolling, glaucoma

Ear and labyrinth disorders:

Uncommon: Ear pain, tinnitus

Respiratory, thoracic and mediastinal disorders

Common: Dyspnoea, epistaxis, cough, nasal congestion, pharyngolaryngeal pain

Uncommon: Wheezing, pneumonia aspiration, pulmonary congestion, respiratory disorder, rales, respiratory tract congestion, dysphonia

Rare: Hyperventilation

Gastrointestinal disorders

Common: Vomiting, diarrhoea, constipation, nausea, abdominal pain, dyspepsia, dry mouth, stomach discomfort

Uncommon: Dysphagia, gastritis, faecal incontinence, faecaloma

Rare: Lip swelling, cheilitis

Renal and urinary disorders

Common: Enuresis

Uncommon: Dysuria, urinary incontinence, pollakiuria

Skin and subcutaneous tissue disorders

Common:	Rash, erythema
Uncommon:	Skin lesion, skin disorder, pruritus, acne, skin discolouration, seborrhoeic dermatitis, dry skin, hyperkeratosis
Rare:	Dandruff

Musculoskeletal and connective tissue disorders

Common:	Arthralgia, back pain, pain in extremity
Uncommon:	Muscular weakness, myalgia, neck pain, joint swelling, posture abnormal, joint stiffness, musculoskeletal chest pain
Rare:	Rhabdomyolysis

Metabolism and nutrition disorders

Common:	Increased appetite, decreased appetite
Uncommon:	Anorexia, polydipsia

Infections and infestations

Common:	Pneumonia, influenza, bronchitis, upper respiratory tract infection, urinary tract infection
Uncommon:	Sinusitis, viral infection, ear infection, tonsillitis, cellulitis, otitis media, eye infection, localised infection, acarodermatitis, respiratory tract infection, cystitis, onychomycosis
Rare:	Otitis media chronic

Vascular disorders

Uncommon:	Hypotension, orthostatic hypotension, flushing

General disorders and administration site conditions

Common: Pyrexia, fatigue, peripheral oedema, asthenia, chest pain

Uncommon: Face oedema, gait disturbance, feeling abnormal, sluggishness, influenza like illness, thirst, chest discomfort, chills

Rare: Generalised oedema, drug withdrawal syndrome, peripheral coldness

Immune system disorders

Uncommon: Hypersensitivity

Rare: Drug hypersensitivity

Reproductive system and breast disorders

Uncommon: Amenorrhoea, sexual dysfunction, erectile dysfunction, ejaculation disorder, galactorrhoea, gynaecomastia, menstrual disorder, vaginal discharge

Psychiatric disorders

Very Common: Insomnia

Common: Anxiety, agitation, sleep disorder

Uncommon: Confusional state, decreased libido, listless, nervousness

Rare: Anorgasmia, blunted affect

Adverse drug reactions reported post-marketing:

Investigations:

Electrocardiogram QT prolongation

Cardiac disorders:

Atrial fibrillation

Blood and lymphatic system disorders:

Thrombocytopaenia, agranulocytosis

Respiratory, thoracic and mediastinal disorders:

Sleep apnoea syndrome

Gastro-intestinal disorders:

Intestinal obstruction, pancreatitis, paralytic ileus

Renal and urinary disorders:

Urinary retention

Skin and subcutaneous tissue disorder:

Alopecia

Endocrine disorder:

Inappropriate antidiuretic hormone secretion

Metabolism and nutrition disorder:

Diabetic ketoacidosis, water intoxication, diabetes mellitus, hypoglycaemia, increased blood cholesterol, increased blood triglycerides

Immune system disorder:

Anaphylactic reaction, angioedema

Psychiatric disorder:

Mania

Nervous System Disorder

Dysgeusia

Eye Disorders

Floppy iris syndrome (intraoperative)

Hepatobiliary disorders:

Jaundice

***Reproductive system and breast disorders*:**

Priapism

Pregnancy, Puerperium and Perinatal Conditions

Neonatal drug withdrawal syndrome

General disorders:

Hypothermia

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Reported signs and symptoms have been those resulting from an exaggeration of the medicine's known pharmacological effects. Symptoms of acute overdosage include drowsiness, sedation, hypotension, tachycardia and extrapyramidal symptoms. In overdose, QT-prolongation and convulsions have been reported. Torsade de pointes has been reported in association with combined overdose of oral RISPERDAL and paroxetine.

In the case of acute overdosage, the possibility of multiple medicine involvement should be considered.

Treatment:

Establish and maintain a clear airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if the patient is unconscious) and administration of activated charcoal together with a laxative should be considered. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible dysrhythmias.

Since there is no known antidote if accidental poisoning or overdosage is suspected, appropriate supportive measures should be instituted. Hypotension and circulatory collapse should be treated with appropriate measures such as intravenous fluids and/or sympathomimetic agents. In case of severe extrapyramidal symptoms, anticholinergic medication should be administered. Close medical supervision and monitoring should continue until the patient recovers.

IDENTIFICATION

RISPERDAL 0,5 mg	A brownish red, oblong, biconvex, half-scored film-coated tablet with "Ris 0,5" inscription on one side and with or without "JANSSEN" inscription on the other side.
RISPERDAL 1 mg	A white, oblong, film-coated half-scored tablet with "Ris 1" inscription on one side and with or without "JANSSEN" inscription on the other side.
RISPERDAL 2 mg	A orange, oblong, film-coated half-scored tablet with "Ris 2" inscription on one side and with or without "JANSSEN" inscription on the other side.
RISPERDAL 3 mg	A yellow, oblong, film-coated half-scored tablet with "Ris 3" inscription on one side and with or without "JANSSEN" inscription on the other side.
RISPERDAL 4 mg	A green, oblong, film-coated half-scored tablet with "Ris 4" inscription on one side and with or without "JANSSEN" inscription on the other side.

PRESENTATION

Cartons containing one or more clear PVC-PE-PVDC/aluminium blisters of 10 tablets each.

STORAGE INSTRUCTIONS

Store at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

0,5 mg – 33/2.6.5/0111

1 mg; 2 mg; 3 mg; 4 mg - 27/2.6.5/0235/6/7/8

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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