

PACKAGE LEAFLET: INFORMATION FOR THE USER

RISSAR 1 mg film-coated tablets

RISSAR 2 mg film-coated tablets

RISSAR 3 mg film-coated tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Rissar is and what it is used for
2. Before you take Rissar
3. How to take Rissar
4. Possible side effects
5. How to store Rissar
6. Further information

1. WHAT RISSAR IS AND WHAT IT IS USED FOR

Rissar (risperidone) belongs to a group of compounds called antipsychotics.

Rissar is used to treat as follows:

- Schizophrenia, by which you may see, hear, feel things which do not exist, to believe in things, which are not true or to feel yourself unusually distrustful and embarrassed;
- Mania, by which you can feel yourself very thrilled, excited, upset, enthusiastic or hyperactive. Mania occurs in an illness called “bipolar disorder” ;
- Short-term treatment (up to 6 weeks) of persistent aggression in patients with Alzheimer’s dementia, inclined to harm themselves or others. Non-pharmacological approaches have to be administered before that;
- Short-term symptomatic treatment (up to 6 weeks) of persistent aggression in children with subaverage intellectual functioning (from the age at least of 5 years) and adolescents with behavioural disorder.

2. BEFORE YOU TAKE RISSAR

Do not take Rissar

- if you are allergic (hypersensitive) to risperidone or any of other Rissar ingredients (as listed in Section 6 hereinafter).

If you are not sure that the above mentioned refers to you ask your doctor or pharmacist, before taking Rissar.

Take special care taking Rissar

Before taking Rissar, tell your doctor or pharmacist:

- If you have any heart problem. For example irregular heartbeat, or if you incline to low blood pressure, or if you take blood pressure medicine. Rissar can cause low blood pressure. Your dosage may need to be adjusted;
- If you are aware of some reasons, inclining you to stroke, as high blood pressure, cardiovascular disorder or problems with blood vessels of the brain;
- Tongue, mouth and face uncontrolled rhythmic movements;
- If you ever had a condition, which symptoms include fever, muscle stiffness, sweating and reduced consciousness level (also known as a Neuroleptic Malignant Syndrome);
- If you have Parkinsonism or Dementia;
- If you suffer from diabetes;
- If you have epilepsy ;
- If you are male and you have ever had a long or painful erection;
- If you have problems with core body temperature or overheating;
- If you have renal problems;
- If you have hepatic problems;
- If you have an abnormal high level of the prolactin hormone in blood or you have a tumor, which could prolactin dependent;
- You or anybody else in your family have had blood clots, if antipsychotics were in connection with blood clots forming.

If you are not sure that any of the above mentioned refers to you, talk to your doctor or pharmacist before taking Rissar.

Rissar can cause weight increase. Considerable weight increase can adversely affect your health. Your doctor has to measure regularly your weight.

Since diabetes or worsening of existing diabetes mellitus have been observed in patients taking Rissar, your doctor should check you for signs of high blood sugar. In patients with existing diabetes mellitus, glucose should be regularly monitored.

Elderly with dementia

In elderly patients with dementia there is an increased risk of stroke. You should not take risperidone if you have dementia, leading to a stroke.

During risperidone treatment you should often consult your doctor.

You should immediately seek medical treatment if you or the person who takes care of you notices a sudden change in your mental state or sudden weakness or numbness of the face, arm or legs, especially on one side, slurred speech even for a short time. These can be symptoms of a stroke.

Children and adolescents

Other reasons for aggressive behaviour need to be mastered before starting risperidone treatment.

If fatigue occurs during risperidone treatment, a change in the time of administration can cause attention improvement.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines.

It is very important to talk to your doctor or pharmacist, if you are taking some of the following medicines:

- Medicines that act on the brain to help you relax (benzodiazepines) or any painkillers (opioids), allergy medications (antihistamines) since risperidone may increase the sedative effects of each of them;
- Medicines that may alter the electrical activity of the heart, such as medicines for malaria, medicines for heart rhythm disorders, allergy;

- Medicines that cause slow heartbeat;
- Medicines that cause low potassium levels (such as certain diuretics);
- Medicines for Parkinson's disease (such as levodopa);
- Medicines for dehydrating (diuretics) used for heart problems or swelling of any part of your body due to too much liquid retention (such as furosemide or chlorothiazid). Rissar when taken alone or with furosemide, may increase the risk of stroke or death in elderly people with dementia.

Listed medicines can reduce risperidone effect:

- Rifampicin (medicine for treating of some infections)
- Carbamazepine, phenytoin (medicines for epilepsy)
- Phenobarbital

If you start or stop taking such medicines you could need different risperidone dose.

Listed medicines can increase risperidone effect:

- Quinidine (used for certain types of heart disease);
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants ;
- Medicines of beta-blockers group (used for high blood pressure);
- Phenothiazines (eg used to treat psychosis or mental health problems);
- Cimetidine, ranitidine (stomach acid blockers).

If you begin or stop taking such medicines you could need different risperidone dose. If you are not sure that any of the above mentioned refers to you, talk to your doctor or pharmacist before taking Rissar.

Taking Rissar with food and drink

You can take this medicine with or without food. You have to avoid alcohol drinking while you are using this medicine.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Ask your doctor for advice if you are pregnant, or are planning to get pregnant or you are breast-feeding. Your doctor shall decide if you can take Rissar.

Reversible trembling, muscles stiffness or feeding problems in the neonate were observed following the use of risperidone during the last trimester of pregnancy.

Driving and using machines

If you are taking Rissar, you may feel dizzy, tired or lightheaded. Do not drive, use instruments or machines before first to talk to your doctor.

Important information about some of the ingredients of Rissar

Rissar contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Rissar 2mg tablets contains color additive called E110 which can cause allergic reactions.

3. HOW TO TAKE RISSAR

Always take Rissar exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor shall tell you how much from the medicine to take and for what period of time. It

depends on your condition and differs by different people.
Swallow the prescribed tablets with a few liquid.

For Schizophrenia treatment

Adults

Normally start dosage is 2 mg/day risperidone. The dosage may be increased on the second day to 4mg. Your dosage can be adjusted by your doctor according to how you feel.

Most patients will benefit from daily doses between 4 and 6 mg.

These common daily doses can be given in one or separated twice.

Your doctor shall tell you what is the best for you.

Elderly

Your starting dose shall be normally of 0.5 mg twice daily. This dosage can be gradually increased by the doctor until it reaches 1 to 2 mg twice daily. Your doctor shall tell you which the best for you.

Children and adolescents

Rissar is not recommended for use in children with schizophrenia below 18 years of age.

For mania treatment

Adults

Your starting dose should be of 2 mg once daily. Your dosage shall be gradually adjusted by the doctor according to your reaction on the treatment. Most of the patients feel better with doses of 1 to 6 mg once daily.

Elderly

Your starting dose should be of 0.5 mg twice daily. Your dosage shall be gradually adjusted by the doctor to 1 mg or 2 mg twice daily according to your reaction on the treatment.

Children and adolescents

Risperidone is not recommended for use in children with bipolar mania below 18 years of age.

For treatment of persistent aggression in patients with moderate to severe Alzheimer's dementia

Adults (including elderly)

Your starting dose shall be normally of 0.25 mg twice daily. Your dosage shall be gradually adjusted by the doctor according to your reaction on the treatment. Most of the patients feel better with dose of 0.5 mg twice daily. Some patients, however, may benefit from doses up to 1 mg twice daily. Risperidone should not be used more than 6 weeks in patients with in Alzheimer's dementia.

Conduct disorder in children and adolescents

The dose depends on your child's weight

Children with weight \geq 50 kg

The starting dose shall be usually of 0.5 mg once daily. This dosage can be gradually adjusted by increments of 0.5 mg once daily. Normally the supportive dose is 0.5 mg to 1 mg once daily. Treatment duration by conduct disorder patients should not be more than 6 weeks.

Risperidone is not recommended in children less than 5 years of age for conduct disorder treatment.

Patients with renal and hepatic impairment

Irrespective of the indication, starting and consecutive dosing should be halved. Dose titration should be slower for these groups of patients.

Risperidone should be used with caution in these groups of patients.

If you take more Rissar than you should:

Contact a doctor immediately. Take the medicine leaflet with you. In case of overdose you can feel somnolent, tired or to receive pathological body movements, you may receive problems by standing or walking, to feel dizzy because of a low heart pressure or to obtain pathological heartbeat or faints.

If you forget to take Rissar:

If you miss a dose, just take it as soon as you remember this. However, if it is already time for the next dose, do not take the missed dose and continue as usually. If you miss two or more doses, contact your doctor.

If you stop taking Rissar

Do not suddenly stop taking this medicine until your doctor tells you so. The symptoms can recur. If your doctor decides to stop this treatment, dose should be gradually reduced for some days.

If you have any further questions on the use of this product, please ask your doctor or pharmacist.

4. POSSIBLE ADVERSE EFFECTS

Like all medicines, Rissar can cause adverse reactions, although not everybody gets them.

Tell immediately to your doctor if:

- If you have veins blood clots, especially in the legs (symptoms include swelling, pain and flushing of the legs), which can be transported through vascular to the lung, which causes chest pain and hard breathing. If you notice any of these symptoms, talk immediately to your doctor.
- If you have dementia and notice sudden change in your intellectual condition or sudden weakness or stiffness of face, hands or legs, especially from the one side or unclear speech even for a short period of time. These can be stroke symptoms.
- If you ever have had condition which symptoms include high fever, muscle stiffness, sweating, reduced consciousness level (also known as neuroleptic malignant syndrome). You may need treatment immediately.
- If you are male and you ever had prolonged and painful erection. This is called priapism. You may need treatment immediately.
- Uncontrolled rhythmic movements of tongue, mouth and face. Maybe you should stop taking risperidone.

Following adverse reactions may occur:

Very common (affect \geq 1 of 10 persons)

- Parkinsonism. It is a medical name, which includes a lot of symptoms. Each individual symptom can occur not more frequently in 1 of 10 patients. Parkinsonism includes: salivary hypersecretion or watery mouth, musculoskeletal stiffness, drooling, convulsions in bending the limbs, slow, reduced or impaired body movements, expressionless face, muscle tightness, neck stiffness, muscle stiffness, small, shuffling, hurried steps and lack of normal movements of the shoulders when walking, persistent blinking in response to tapping of the forehead (an abnormal reflex);
- Headache, difficulty falling asleep or staying awake.

Common (affect 1 to 10 persons of 100)

- Drowsiness, fatigue, restlessness, inability to sit still, irritability, anxiety, drowsiness, dizziness, disturbance in attention, feeling of fatigue, sleep disorders;
 - Vomiting, diarrhea, constipation, nausea, increased appetite, abdominal pain or discomfort, sore throat, dry mouth;
 - Weight gain, increase body temperature, decreased appetite;
 - Difficult breathing, lung infection (pneumonia), flu, respiratory infection, blurred vision, nasal congestion, nosebleeds, cough;
 - Urinary tract infection, enuresis;
 - Muscle spasms, involuntary movements of the face or hands and legs, joint pain, back pain, swelling of hands and legs, pain in hands and legs;
 - Rash, redness of the skin;
 - Rapid heartbeat, chest pain;
 - Increased level of blood prolactin.
- Uncommon (affect 1 to 10 persons of 1,000)**
- Excessive water drinking , faecal incontinence, thirst, hard stools, hoarseness or change in voice;
 - Diabetes mellitus, high blood sugar;
 - Lung infections caused by inhaling food into the airways, bladder infection, ‘pink eye’, sinus infection, viral infection, ear infections, tonsil infections, infections under the skin, eye infections, gastric infection, secretions from the eyes, fungal nail infections;
 - Abnormal electrical conduction of the heart, drop in blood pressure upon standing, low blood pressure, dizziness after body position changing, abnormal electrical activity of the heart (ECG), abnormal heart rhythm, rapid heartbeat, feeling of heart palpitation, rapid or slow heartbeat;
 - Urinary incontinence, pain during urination, frequent urination;
 - Confusion, attention deficit disorder, depresses level of consciousness, excessive drowsiness, nervousness, high mood (mania) , lack of energy and interest;
 - Elevation of liver enzymes, decreased white blood cell count, low haemoglobin and low count of red blood cell (anemia), increased eosinophils (special white blood cells), elevated creatinine levels, decreased platelets (blood cells that help to stop bleeding);
 - Muscle weakness, muscle pain, ear pain, neck pain, joint swelling, abnormal posture, joint stiffness, pain in muscles and bones in the chest, chest discomfort;
 - Skin lesion, skin impairment, dry skin, intense skin itching, acne, hair loss, skin inflammation caused by pests, discoloration of the skin, thickening of the skin, redness, decreased skin sensitivity to touch and pain, oily skin inflammation;
 - Absence of menstruation, sexual dysfunction, erectile dysfunction, ejaculation disorder, breast secretion, breast enlargement in men, decreased sexual desire, irregular menstruation, leucorrhoea;
 - Fainting, gait disturbance, sluggishness, decreased appetite resulting in malnutrition and low body weight, feeling strange, balance disorder, allergy, edema, speech disorder, chills, impaired coordination;
 - Painful oversensitivity to light, increased blood flow to the eyes, eyes swelling, dry eyes, tears production increased;
 - Damage to the airways, lung congestion, wheezing, rattling lung, respiratory congestion, difficulty in speaking, difficulty in swallowing, wet cough, rough wheezing when breathing, flu-like illness, sinus congestion;
 - Unresponsive to stimuli, loss of consciousness, sudden swelling of lips and eyes along with difficulty breathing, sudden weakness or numbness of the face, hands or legs, especially on one side, or periods of slurred speech that lasted less than 24 hours (they are called mini-strokes or strokes), involuntary movements of face, hands or legs, ringing in the ears, face edema;

- Inability to urinate or incomplete bladder emptying.

Rare (affect 1 to 10 persons of 10,000)

- Inability to reach orgasm, menstrual disorder;
- Dandruff;
- Drug allergy, coldness in hands and legs, lip swelling, lips inflammation;
- Glaucoma, reduced visual clarity, eyelid margin crusting, eye rolling;
- Lack of emotion;
- Change in consciousness with increased body temperature and twitching of muscles, edema all over the body, drug withdrawal syndrome, decreased body temperature;
- Fast shallow breathing, hard breathing during sleep, chronic otitis media;
- Obstruction of intestine;
- Reduced blood flow to the brain;
- Decreased white blood cell count, inappropriate secretion of a hormone that controls urine volume;
- Breakdown of muscle fibres and pain in muscles (rhabdomyolysis), movement disorder;
- Coma due to uncontrolled diabetes;
- Yellowing of the skin and the eyes (jaundice);
- Inflammation of the pancreas;
- Low blood sugar.

Very rare (affect < 1 of 10,000 persons)

- Life threatening complications of uncontrolled diabetes.

Unknown frequency (frequency cannot be estimated from the available data)

- Severe allergic reaction resulting in difficulty in breathing and shock;
- No granulocytes (a type of white blood cell to help you against infection);
- Prolonged and painful erection;
- Dangerously excessive intake of water.

If any of the adverse reactions gets serious, or if you notice any adverse reactions not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE RISSAR

Keep out of the reach and sight of children.

This product does not require any special storage conditions.

Do not use Rissar after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Do not remove tablets from blisters before.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rissar contains

- The active substance is risperidone.

Each film-coated tablet Rissar contains 1 mg, 2 mg or 3 mg risperidon.

- Other substances are:

1 mg film-coated tablet contains:

Tablet core - Magnesium stearate; Silica, colloidal anhydrous; Cellulose, microcrystalline (E460); Lactose monohydrate; Croscarmellose sodium.

Film-coating – Hydroxypropylcellulose; Titanium dioxide.

2 mg film-coated tablet contains:

Tablet core - Magnesium stearate; Silica, colloidal anhydrous; Cellulose, microcrystalline (E460); Lactose monohydrate; Croscarmellose sodium.

Film-coating - Hydroxypropylcellulose; Titanium dioxide; Colour sunset yellow Al lake FCF E 110 CI 15985.

3 mg film-coated tablet contains:

Tablet core - Magnesium stearate; Silica, colloidal anhydrous; Cellulose, microcrystalline (E460); Lactose monohydrate; Croscarmellose sodium; Colour quinoline yellow Al lake E 104 CI 47005.

Film-coating - Hydroxypropylcellulose; Titanium dioxide; Colour quinoline yellow Al lake E 104 CI 47005.

What Rissar looks like and contents of the pack

Rissar 1 mg film-coated tablets

The film-coated tablets are white, round, biconvex, film-coated tablets.

Rissar 2 mg film-coated tablets

The film-coated tablets are yellowish-orange, round, biconvex, film-coated tablets with bisection line on the one side.

Rissar 3 mg film-coated tablets

The film-coated tablets are yellow, round, biconvex, film-coated tablets with bisection line on the one side.

The tablets are packed in press-through blisters (AL/PVC), containing 10 tablets on each blister.

The printed cardboard box contains 20 tablets (2 - two blisters) and a leaflet for the patient.

Marketing authorization holder and manufacturer

Manufacturer

ALKALOID- INT d.o.o.

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For any information about this medicine, please contact the Marketing Authorization Holder:

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