

i PACKAGE LEAFLET:
Information for the patient

RISPERIDON

Oral solution - 1 mg / ml

(Risperidon)

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 becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Risperidon is and what it is used for
2. Before you take Risperidon
3. How to take Risperidon
4. Possible side effects
5. How to store Risperidon
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1. WHAT RISPERIDON IS AND WHAT IT IS USED FOR

Risperidon belongs to the group of medications known as antipsychotic agents. Risperidon is used in:

- schizophrenia - which can cause symptoms such as hallucinations (e.g., hearing, seeing, or sensing things that are not there), delusions, unusual suspiciousness, and emotional withdrawal. People with this condition may also feel depressed, anxious, or tense;
- bipolar disorder - causes alternating episodes of mania and depression.
- short-term treatment of behavioural problems (such as verbal or physical aggression, suspiciousness, and agitation) in people with severe dementia.

Medications like risperidone are thought to work by correcting the function of nerve pathways in certain areas of the brain. Your doctor may have suggested this medication for conditions other than the ones listed above. If you have not discussed this with your doctor or are not sure why you are taking this medication, talk to your doctor.

Do not stop taking Risperidon without consulting your doctor.

2. BEFORE YOU TAKE RISPERIDON

Do not take Risperidon if:

- you are hypersensitive to risperidone or to any of the other ingredients of Risperidon;
- if you are breastfeeding.

Take special care with Risperidon

Be sure to inform your physician of all your medical conditions before you begin taking a medication. Some conditions can affect how you should take this medication, so the doctor should be informed about:

low blood pressure - risperidone may cause a lowering of blood pressure when rising from a sitting or lying position, or a racing heart rate, especially when the treatment lasts for several weeks. If you feel dizzy or lightheaded or feel your pulse is racing, call your doctor. Because this medication can cause dizziness or lightheadedness, do not get up too quickly after you have been sitting or lying for prolonged periods;

drowsiness / reduced alertness - risperidone may interfere with activities requiring mental alertness. Those taking this medication should not be driving or operating machinery; **neuroleptic malignant syndrome** - risperidone, like other antipsychotic medications, can cause a potentially fatal syndrome known as neuroleptic malignant syndrome (NMS). Symptoms include: high fever, muscle stiffness, confusion or loss of consciousness, sweating, racing or irregular heartbeat, and fainting.

Parkinson's disease - risperidone may cause a deterioration in the condition of people with Parkinson's disease and should therefore be used with caution;

seizures - risperidone may increase the risk of seizures,

especially in people who have had seizures in the past. People who are at risk of seizures who take this medication should be closely monitored by their doctor;

tardive dyskinesia - this syndrome consisting of potentially irreversible, involuntary, repetitive movements of the face and tongue muscles, may develop in people who take certain antipsychotic medications. This syndrome appears most commonly in elderly, especially women. The risk of developing this syndrome rises with increasing doses and long-term treatment. If signs and symptoms of this syndrome develop during treatment with risperidone, contact your doctor as soon as possible;

weight gain - with long-term treatment, average weight gain is 2.3 kg; **children and adolescents** - the safety and effectiveness of risperidone for use by children and adolescents have not been established.

elderly - there may be a higher risk of strokes, heart attacks, and deaths associated with the use of risperidone by people with dementia. Talk to your doctor about the risks and benefits of using this medication. If you notice the following signs and symptoms, get medical attention immediately:

signs of a stroke - sudden weakness or numbness in the face, arms or legs (often on one side of the body), speech problems, vision problems, balance problems or dizziness; confusion; sudden severe headache with no known cause; *signs of a heart attack* - discomfort or pain in the chest, back, neck, jaw, arms, or stomach; sweating; shortness of breath; nausea; lightheadedness; feeling of impending doom.

Taking other medicines

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

It is especially important that your doctor be aware if you are being treated with:

- Levodopa and other dopamine agonists: risperidone may antagonize the actions of levodopa and other dopaminergics.
- CNS depressants and alcohol: the central effects of other CNS depressants, including alcohol, may be enhanced by risperidone.
- Antihypertensives: risperidone may also enhance the effects of antihypertensives.
- Drugs that prolong QT interval: there may be an increased risk of QT prolongation when risperidone is given with other drugs that are known to cause this effect.
- Carbamazepine and hepatic enzyme inducers: increase the metabolism of risperidone, resulting in reduced risperidone levels.
- Fluoxetine: may increase the plasma concentrations of the anti-psychotic fraction by raising the concentration of risperidone.
- Paroxetine: plasma concentration of risperidone may be increased by paroxetine (increased risk of toxicity).
- Phenothiazines, tricyclic antidepressants and some beta-blockers: may increase the plasma concentrations of risperidone, but don't raise its antipsychotic fraction.
- Highly protein-bound medicines: when risperidone is taken together with other highly protein-bound medicines (e.g. diazepam, warfarin, digitoxin, imipramine and propranolol), are not clinically effective for the displacement of other agents from the plasma proteins.

Taking Risperidon with food and drinks

This medicine can be taken with or without meals. While using Risperidon, alcohol should be avoided. The oral solution should not be taken with Cola or tea

Pregnancy and breastfeeding

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medication.

There are reported extrapyramidal effects in neonates when taken in third trimester. Risperidone should not be used during pregnancy without carefully assessing the potential risk / benefit from your doctor. Ask your doctor for advice before taking any medicinal product.

Breastfeeding

Tell your doctor or pharmacist if you are breastfeeding. Risperidone is excreted into breast milk, therefore, it should not be taken during breastfeeding.

Driving and using machines

Risperidone may interfere with activities requiring mental alertness. During treatment with Risperidon may occur: blurred vision, drowsiness, concentration difficulties, dizziness. Those taking this medication should not drive or operate machinery until they have determined whether or not it affects them in this way.

3. HOW TO TAKE RISPERIDON

Always take Risperidon as your doctor has told you. If you are not sure, ask your doctor or pharmacist. The usual doses are described below:

Schizophrenia:

Adults: Start with 2 mg per day. On the second day, this may be increased to 4 mg per day. The usual optimal dose is 4-6 mg per day. Doses greater than 10 mg per day did not increase the therapeutic effect, but can be used if the benefit is greater than the risk. It should not be used more than 16 mg per day. Administration is made as single dose or divided into two doses. If sedation is required, benzodiazepine can be administered concomitantly.

Elderly: Initially 0.5 mg twice daily. It can be increased with 0.5 mg twice daily but not more than 1-2 mg twice daily.

Children under 15 years old: not recommended.

Manic episodes (Bipolar disorder):

Adults: Initially 2 mg once daily. Adjust dose if indicated at intervals of 24 hours. Recommended dose 2-6 mg daily.

Children and adolescents under 18 years old: not recommended.

Behavioural disturbances:

Patients weighing less than 50 kg

Initial dose is 0.25 mg once daily and it can be increased by an additional 0.25 mg on the second day. Usual maintenance dose, 0.5 mg once daily (range 0.25 – 0.75 mg/day).

Patients weighing 50 kg or more

Initial dose 0.5 mg once daily and it can be increased by an additional 0.5 mg on the second day. Usual maintenance dose, 1 mg once daily (range 0.5 – 1.5 mg daily).

Children under 5 years old: not recommended.

Since the dose may however need to be increased or reduced, your doctor will advise you according the circumstances.

Administration in hepatic or renal impairment.

Regardless of the disease to be treated, all starting doses and following doses of risperidone should be halved. Dose increases should be gradual in these patients. Risperidone should be used with caution in this patient group.

Instructions for use and handling

Open the bottle.

Insert the pipette (or syringe) into the bottle. While holding the bottom ring, pull the top ring up to the mark corresponding to the number of mL you need to take. Remove the entire pipette (or syringe) from the bottle. Empty the pipette (or syringe) into any non- alcoholic drink, except for Cola or tea, by sliding the upper ring down. Close the bottle. Rinse the pipette (or syringe) with plenty of water.

If you take more Risperidon than you should:

If you have taken more Risperidon than you should, or if children have been taking this medicine by accident, please contact your doctor, the hospital or call the emergency for detoxification from excessive risperidone.

Symptoms of acute overdose include drowsiness, sedation, hypotension, tachycardia and extrapyramidal symptoms, and in some rare cases the QT-prolongation.

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 arrhythmias.

If you forget to take Risperidon

If you forget a dose (or more doses), take the next dose when it is the usual time to take it.

Do not take a double (or a larger) dose to make up with the forgotten dose(s).

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, risperidone can cause side effects, although not everybody gets them.

The majority of side effects are dose-related and disappear when the dose is reduced or the treatment discontinued. Some side effects can occur at the beginning of treatment and resolve spontaneously as the treatment continues.

The following side effects may include less than 1% of people who use this medication.

In people with schizophrenia, the most common side effects are: agitation, anxiety, difficulty in sleeping, headache, runny nose. Check with your doctor as soon as possible if any of the following side effects occur: muscle twitching or spasms (of the face, neck, or body), abnormal movements of the face or tongue, large changes in body temperature, trouble speaking or swallowing, difficulty moving eyes, changes in vision, loss of balance control, mask-like face, menstrual changes, mood or mental changes.

Stop taking the medication and seek immediate medical attention if any of the following occurs: confusion, difficult or fast breathing, an erection that lasts more than 4 hours without sexual stimulation, fast or irregular heartbeat, high fever, loss of bladder control, reduced consciousness, seizures, signs of a stroke, signs of a heart attack, suicidal thoughts, unusually high or low blood pressure.

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

5. HOW TO STORE RISPERIDON

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton box.

Store in temperature 15 – 30°C

Store in the original package in order to protect from light and humidity.

6. FURTHER INFORMATION

What Risperidon contains – Oral solution 1 mg / ml

The active substance is risperidone.

1 ml oral solution contains 1 mg risperidone.

The other excipients are: benzoic acid, tartaric acid, sodium hydroxide, purified water.

Contents of the pack

Carton box with 1 amber glass bottle 30 ml and 1 calibrated pipette (or syringe).

Explanatory of the illustration icons on the packaging:



According to medical prescription.



Content.



Warning.



Oral drops.

Marketing Authorisation Holder and Manufacturer:



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