

RISPERON

Risperidone Oral Solution 1 mg/mL



What is in this leaflet

This leaflet answers some common questions about Risperon.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Risperon against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Risperon is used for

Risperon Oral Solution contains the active ingredient Risperidone. It belongs to a group of medicines called antipsychotic agents.

It is used for:

- treatment of sudden (acute) and long-term (chronic) schizophrenia and other types of related psychoses. These are illnesses with disturbances in thinking, feelings and behaviour.
- treatment and long term control of mania in bipolar disorder. This condition is characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgement including

disruptive or aggressive behaviours.

- treatment of behavioural problems, such as aggression (through spoken words or physical actions), morbid suspiciousness, agitation or wandering, in Alzheimer patients with declining mental ability (dementia).
- treatment of conduct and other disruptive behaviours such as aggression, impulsivity and self-injurious behaviours in children (over 5 years of age), adolescents and adults who are intellectually disabled.
- treatment of autism in children and adolescents.

Risperon helps to correct a chemical imbalance in the brain which is thought to be associated with these conditions.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you take Risperon

When you must not take it

Do not take Risperon if you are allergic to Risperidone or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not breast-feed if you are taking this medicine.

The active ingredient in Risperon passes into breast milk and there is a possibility that your baby may be affected.

Do not take Risperon after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially any of the following:

- dementia and have a history of the following: diabetes, stroke or a disorder that affects the blood supply to the brain (TIA), abnormally low blood pressure
- dementia as a result of Lewy body disease (a certain disorder affecting the nerve cells in the brain)
- Parkinson's disease
- cardiovascular disorder (e.g. inability of the heart to pump blood properly, heart attack, heart rhythm disorders, lack of fluid in the body tissues (dehydration), abnormal low volume of circulating blood (hypovolaemia) or a disorder affecting the blood vessels in the brain)
- low blood pressure (hypotension) or high blood pressure (hypertension)

- reduced liver or kidney function
- epilepsy (seizures)
- diabetes
- restlessness or difficulty sitting still
- intraoperative iris syndrome (a complication that may occur during cataract extraction)
- tardive dyskinesia (uncontrollable twitching or jerking movements of the arms and legs)
- if you are using drugs that can prolong the QT interval (ask your doctor or pharmacist about this) or if you have a heart condition, a heart rhythm disorder or abnormal low levels of potassium in the blood
- if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- breast cancer
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- low white blood cell count.

Tell your doctor if you are pregnant or plan to become pregnant. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Risperon.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Risperon may interfere with each other. These include:

- diuretic medication such as furosemide, used to treat heart problems or to treat

swelling of parts of the body caused by the build-up of too much fluid

- medicines to lower your blood pressure
- medicines used to treat Parkinson's Disease
- medicines used to treat epilepsy
- carbamazepine, a medicine mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face)
- fluoxetine and paroxetine, medicines used to treat depression, panic disorder, anxiety or obsessive-compulsive disorder
- some sleeping tablets, tranquillisers, pain-killers, antihistamines
- medicines used to treat bacterial and fungal infection
- other medicines to treat mental illness or psychotic conditions
- medicines to relieve severe nausea and vomiting.

These medicines may be affected by Risperon or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Risperon

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Take Risperon exactly as your doctor has prescribed. Never change the dose yourself. Do not increase the dose more quickly than you have been told.

Your doctor will decide the dose suitable. They will be able to tell you:

- how many millilitres to take at each dose
- how many doses to take each day
- when to take each of your doses.

The dose that your doctor prescribes will generally depend on the condition you are being treated for, and how you respond to treatment. Your doctor may adjust your dose during therapy, until the desired effect is obtained.

Risperon should not be used in children under 15 years with schizophrenia. There is little experience with the product in this group.

Risperon should not be used in children under 5 years with disruptive behaviour disorders. There is little experience with the product in this group.

How to take it

It does not matter if you take Risperon before or after food.

Measure the amount (dose) of Risperon oral solution that your doctor has prescribed (See "How to use" section). Mix the dose of Risperon oral solution with a non-alcoholic drink before swallowing and take immediately. **Do not mix with tea.**

Alcohol should be avoided while taking Risperon.

How to use

The solution comes with a syringe (pipette). This should be used to help you measure the exact amount of medicine you need.

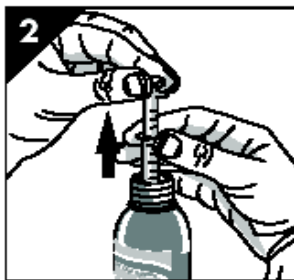
Instructions for using the pipette with Risperon

1. Remove the child-resistant cap from the bottle by pushing down on the cap while turning it anticlockwise (Figure 1).

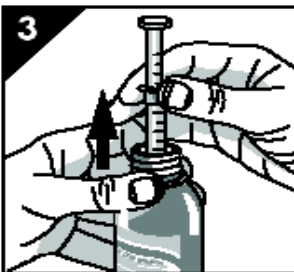


Place the bottle on a flat surface.

2. Remove pipette from pipette holder.
3. Insert the pipette into the bottle.
4. While holding the lower ring, pull the top ring upwards until the mark that matches the number of mg or ml to be taken is just visible (Figure 2).



5. Holding the lower ring, remove the whole pipette from the bottle (Figure 3).



6. Empty the contents of the pipette into a glass of water by pushing the top ring of the pipette right down. **Do not mix with tea.**
7. Close the bottle and clean the dosing pipette by rinsing with water. Replace the child-resistant cap on the bottle by screwing it down clockwise until it locks fully.

When to take it

Your doctor will tell you what time of the day, and how often to take Risperon.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If you forget to take Risperon, take the missed dose as soon as you remember instead of your next dose. Then go back to taking it as you would normally.

Do not take a double dose to make up for the one you missed.

This may increase the chance of you getting an unwanted side effect.

If you forget to take Risperon for 5 days or more, tell your doctor before starting your medicine again.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Risperon. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, sleepiness, increased heart rate, excessive trembling or muscle stiffness, very low blood pressure causing fainting or unconsciousness.

While you are using Risperon

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Risperon.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking Risperon.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Risperon.

It may affect other medicines used during surgery.

If you become pregnant while taking Risperon, tell your doctor immediately.

Pre-menopausal women should tell their doctor if they do not have a period for more than six months while taking Risperon.

Try to eat a moderate diet.

Risperon can cause weight gain.

Tell your doctor immediately if you develop uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking antipsychotic medicines, including Risperon. This condition is more common during long term treatment, especially in elderly women. If detected early, these symptoms are usually reversible. However in very rare cases, this may be permanent.

Things you must not do

Do not take Risperon to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not drink alcohol.

This medicine can increase the effects of alcohol.

Things to be careful of

Be careful driving or operating machinery until you know how Risperon affects you.

Risperon may cause dizziness, light-headedness or drowsiness in some people. If you have any of these symptoms, do not drive a car,

operate machinery, or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Risperon.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- difficulty sleeping
- headache
- trembling
- drowsiness, tiredness, difficulty in concentrating
- changes in your behaviour such as agitation or anxiety
- muscle or joint stiffness
- restlessness in the legs
- change in gait
- weight gain
- indigestion, nausea, abdominal pain, constipation
- frequent urination
- inability or pain when passing urine
- unusual secretion of breast milk
- breast swelling
- sexual dysfunction, priapism (prolonged erection).

These side effects are usually mild but may require medical attention.

Tell your doctor as soon as possible if you notice any of the following:

- missed or irregular menstrual periods

- involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk
- excessive thirst
- light-headedness or dizziness on standing up, that passes after a few seconds or after sitting down again (fall in blood pressure).

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- changes in heart rate, including fast or slowed heart rate, and heart beat irregularities
- change in body temperature including abnormally high temperature
- symptoms of an allergic reaction which may include: rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body. If you have any of these symptoms, you may have had a serious allergic reaction to Risperon
- sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)
- in elderly patients with dementia, occurrence of the following even for a short period time: sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

Do not hesitate to report any other side effects to your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Risperon

Storage

Keep Risperon oral solution in the original packaging until it is time to take it.

If you take the bottle out of the box it may not keep well.

Keep the solution in a cool dry place where the temperature stays below 30°C. Do not refrigerate or freeze.

The shelf life after first opening the bottle is four months.

Do not store Risperon or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

The oral solution is a clear, colourless solution. It is available in a bottle of 30 ml.

A pipette is enclosed so that the correct quantity of solution can be measured.

Ingredients

The active ingredient in Risperon oral solution is Risperidone. 1 ml of

the oral solution contains 1 mg
Risperidone.

It also contains:

- tartaric acid (E334)
- benzoic acid (E210)
- hydrochloric acid
- purified water.

This medicine does not contain
lactose, sucrose or gluten.

If you want to know more

Should you have any questions
regarding this product, please
contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of Information

15 October 2018 (Based on data
sheet dated 15 October 2018)