

RISTOR Oral Solution 1mg/ml

Risperidone (1mg per ml)

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What RISTOR is used for

RISTOR is used to treat a group of disorders called psychoses (e.g. schizophrenia). These are brain function disorders relating to thought, feeling and/or action, such as confusion, impaired perception (like hearing the voice of someone who is not there), unusual suspiciousness, alienation from society, and being excessively introverted, as well as the resulting disturbed mental state, anxiety, and tension.

RISTOR may be taken for both sudden (acute) and long-lasting (chronic) psychotic disorders.

In addition, after symptoms have been relieved, RISTOR is used to keep the disorder under control, i.e. to prevent its recurrence.

RISTOR is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders.

RISTOR is used to treat short-term treatment (up to 6 weeks) of long-term aggression in intellectually disabled children (at least 5 years of age) and adolescents with conduct disorder.

How RISTOR works

Acts in the central nervous system, RISTOR works on the balance of chemical substances which act on the nervous system in the brain.

Before you use RISTOR

-When you must not use it

Do not take RISTOR if you are allergic to risperidone or any of the other ingredients of this medicine.

-Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant, planning to get pregnant or are breastfeeding.

Risperidone should not be used during pregnancy unless clearly necessary. The following symptoms may occur in newborn babies, of mothers that have used Risperidone in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

There are no data available on adverse reactions in breast-feeding infants. Therefore, the advantage of breast-feeding should be weighed against the potential risks for the child.

-Before you start to use it

Talk to your doctor or pharmacist before taking RISTOR if you (are):

- in need to take cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken risperidone.
- elderly patients with dementia, there is an increased risk of stroke.
- taking furosemide (a 'water pill,' that is used to reduce the swelling and fluid retention caused by various medical problems, including heart or liver disease).
- individual with risk factor of stroke.
- having heart problem. Examples include an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure.
- know that you have had low levels of white blood cells in the past.
- have ever experienced involuntary movements of the tongue, mouth and face.
- have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome).
- have Parkinson's disease or dementia.

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- sweating, or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome).
- diabetic
- have an abnormally high level of the hormone prolactin in your blood or if you have a possible prolactin-dependent tumour.
- have low levels of potassium or magnesium in the blood.
- have epilepsy
- are a man and you have ever had a prolonged or painful erection.
- have problems controlling your body temperature, are prone to overheating, or are, or maybe, exposed to very high temperatures or strenuous exercise.
- feel nausea and vomiting
- kidney and liver problem.
- has a history of blood clots.
- under pediatric population. There is a potential effect on growth and maturation.

-Taking other medicines

Inform your doctor or pharmacist before taking this medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and RISTOR may interfere with each other. They may be affected by RISTOR or may affect how well it works.

You should talk to you doctor or pharmacist if you are taking any of the following :

- Medicines that may change the electrical activity of your heart, such as medicines for heart rhythm problems (such as quinidine, disopyramide, procainamide, propafenone, amiodarone, sotalol), tetracyclic antidepressants (e.g. maprotiline), allergies (antihistamines), antimalarials (quinine, mefloquine), some antidepressants such as tricyclic antidepressants (e.g. amitriptyline) or other medicines for mental health problems.
- Medicines that work on your brain such as to help you calm down (benzodiazepines) or some medicines

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for pain (opiates), medicines for allergy (some antihistamines) and alcohol.

- Levodopa (medicines for Parkinson's disease) and dopamine (chemical messenger between nerve cells).
- medicines that cause low blood potassium (such as certain diuretics).
- Paliperidone (a medicine used to treat mental problems).
- antidepressants such as paroxetine and Highly Protein Bound Drugs.
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate).
- Antibacterials (medicines used to for treating bacterial infections).
- Anticholinesterases (Chemicals that prevent the breakdown of the neurotransmitter acetylcholine)
- Antiepileptics (medicines used for treatment of epilepsy)
- Antipsychotics (medicines used to manage psychosis)
- Antivirals (medicines used to for treating viral infections).
- Beta blockers (medicines to manage abnormal heart rhythms, and to protect the heart from a second heart attack after a first heart attack).
- Calcium channel blockers (medications to decrease blood pressure in patients with hypertension)
- Gastrointestinal drugs (medicine used to treat disorder of the digestive system)
- Digitalis glycosides (to treat mild to moderate heart failure)
- Lithium (used to treat mood disorders)
- Furosemide (a 'water pill,' that is used to reduce the swelling and fluid retention).

How to use RISTOR

-How much to use

Always use RISTOR exactly as your doctor has prescribed. You should check with your doctor or pharmacist if in doubt.

The usual dose:

For psychoses (e.g. schizophrenia) in adults, treatment starts gradually. For example: 2 mg is taken the first day and 4 mg the second day. From then on, the dose can remain unchanged or further modified if necessary.

For long-term treatment, 4 to 6 mg daily is the usual dose. A lower dose, however, may be sufficient.

Your doctor should advise you which is the best for you.

For psychoses in elderly people, it is generally best to start with 0.5 mg twice a day. The medication can be gradually increased to 1 to 2 mg twice a day. Your doctor will tell you how much solution is appropriate to your situation. Experience with this treatment in children aged less than 18 years is lacking.

For the treatment of bipolar mania, it should be administered on a once daily schedule, starting with 2 mg risperidone. Dosage adjustments, if indicated, should occur at intervals of not less than 24 hours and in dosage increments of 1 mg per day.

Risperidone can be administered in flexible doses over a range of 1 to 6 mg per day to optimise each patient's level of efficacy and tolerability. Daily doses over 6 mg risperidone have not been investigated in patients with manic episodes.

For bipolar mania in elderly people, it is best to start with 0.5 mg twice a day. The medication can be gradually increased to 1 to 2 mg twice a day. Your doctor will tell you how much solution is appropriate to your situation.

For the treatment of conduct disorder in children and adolescent, the dose will depend on your child's weight:

For children who weigh 50 kg or more

- The starting dose will normally be 0.5 mg (0.5 ml of RISTOR oral solution 1 mg/ml) once a day.
- The dose may be increased every other day in steps of 0.5 mg per day
- The usual maintenance dose is 0.5 mg to 1.5 mg once a day.

For children who weigh less than 50 kg

- The starting dose will normally be 0.25 mg (0.25 ml of RISTOR oral solution 1 mg/ml) once a day.
- The dose may be increased every other day in steps of 0.25 mg per day.

- The usual maintenance dose is 0.25 mg to 0.75 mg (0.25 ml to 0.75 ml of RISTOR oral solution 1 mg/ml) once a day.

Children under 5 years old should not be treated with RISTOR for conduct disorder.

For people with reduced or weakened kidney or liver function

Your doctor will tell you how much solution is appropriate to your particular situation.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking RISTOR as your doctor recommended. If symptoms persist, consult your doctor.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

In overdose, one or more of the following signs may occur: reduced consciousness, drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, fast beating heart, and low blood pressure. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported. Overdose can happen if you are taking other medications together with RISTOR. If you experience the above signs, please contact your doctor.

In the meantime, you can always start treating these disturbances with activated charcoal, which absorbs any medicine still in the stomach.

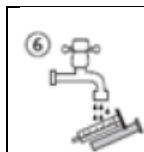
While you are using RISTOR

Things you must do

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- Inform your doctor or pharmacist if symptoms persist after taking this medication.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking RISTOR
- Tell your doctor immediately if you become pregnant while taking this medication.



Wash the syringe with water and let it dry before you use it again. Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.

- Tremor (shaking)
- Blurry vision
- Rapid heart rate, High blood pressure, Shortness of breath
- Sore throat, Cough, Nosebleeds, Stuffy nose
- Abdominal pain or discomfort,
- Vomiting, Nausea, Constipation, Diarrhea
- Indigestion, Dry mouth
- Rash
- Incontinence (lack of control) of urine
- Swelling of the body, arms or legs, Fever, Weakness, Fatigue (tiredness), Pain
- Fall.

Instruction for Use

	Open the bottle by pressing the cap and turning it anticlockwise.
	Insert the syringe adaptor into the bottle neck.
	Take the syringe and put it in the adaptor opening.
	Turn the bottle upside down.
	Fill the syringe with a small amount of solution by pulling the piston down. Then push the piston upward in order to remove any possible bubbles. Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor.
	Turn the bottle the right way up. Remove the syringe from the adaptor. Empty the syringe into a drink of water or orange juice and use immediately.

- Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor.
- Do not give RISTOR to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Weight Gain

Try to eat moderately, since RISTOR could induce weight gain.

Driving or using machines

RISTOR might affect your alertness or driving ability. You are therefore advised not to drive or to operate machines before your doctor has assessed your personal sensitivity to RISTOR.

Side effects

Like all medicines, RISTOR can cause side effects. Listed below are adverse reactions related to RISTOR treatment. Should you experience these symptoms, please consult your doctor.

Very Common (in more than 1 in 10 people)

- Difficulty falling or staying asleep
- Parkinsonism: This condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles;
- Feeling sleepy, or less alert.

Common (in more than 1 in 100 people but less than 1 in 10 people)

- Sinus infection, Urinary tract infection
- Sleep disorder, Anxiety, Restlessness
- Dystonia: sustained involuntary contraction of muscles
- Dizziness
- Dyskinesia: involuntary muscle movements

Elderly

- Lung infection
- Decreased appetite
- "Pink eye"
- Skin redness

Talk to your doctor or pharmacist if you experience:

- Increases in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increased hunger, and frequent urination)
- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- Trouble breathing during sleep (sleep apnoea)
- Difficulty or inability to pass urine (urinary retention)

During a long treatment, RISTOR might cause involuntary twitching in the face. Should this happen, consult your doctor.

Very rarely a state of confusion, reduced consciousness, high fever and stiff muscles might occur. If this happens, contact a doctor right away and tell him or her that you are taking RISTOR.

In very rare cases, high blood sugar has been reported. Contact your doctor if you experience symptoms, such as excessive thirst or urination.

There are other possible side effects of RISTOR. For more information, ask your doctor or pharmacist.

It should be emphasized, though, that most people will not have any such

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problems. However, do not hesitate to report any undesired effects to your doctor or pharmacist. Further, if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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NPRA (R2) 21/083

Storage and disposal of RISTOR

Storage

Keep the container tightly closed. Store below 30°C. Protect from light.

Keep medicine out of reach of children.

-Disposal

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.

Product description

-What it looks like

A clear colourless liquid.

-Ingredients

-Active ingredient

Risperidone

-Inactive ingredients

Benzoic acid, Hydrochloric acid solution and purified water

Dosage form

Oral solution

Packaging

60ml HDPE translucent bottle with child lock cap and induction seal. The bottle is packed in a preprinted carton together with a press in bottle adaptor, a syringe and a piece of package insert.

-MAL number

MAL220206012AZ

Manufactured by and Product

Registration Holder

KCK Pharmaceutical Industries Sdn. Bhd.