

RISPERIDONE GENERICHEALTH

(risperidone) film-coated tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Risperidone generichealth. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

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

Your doctor and pharmacist have more information.

Keep this leaflet with your medicine.

You may need to read it again.

What Risperidone generichealth is used for

Risperidone generichealth belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

It is used for:

- treatment of sudden (acute) and long term (chronic) schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action.
- short term treatment of acute mania associated with bipolar 1 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 in patients with a decline in mental ability (dementia) caused by Alzheimer's disease. These problems include: aggression through words or action, morbid suspiciousness, agitation or wandering.
- treatment of conduct and other disruptive behaviours such as aggression, impulsiveness and self-injury in children (over 5 years old), adolescents and adults who are intellectually disabled.
- treatment of behavioural symptoms of autism in children and adolescent.

Risperidone generichealth helps to correct a chemical imbalance in the brain associated with these conditions.

This medicine has been approved for the uses mentioned above. However, your doctor may prescribe it for another use. It is only available with a doctor's prescription.

If you want more information, ask your doctor.

Risperidone generichealth is not addictive.

Before you take Risperidone generichealth

When you must not take it

Do not use Risperidone generichealth:

- if you know you are allergic to any of its ingredients (see the last section of this leaflet for a list of ingredients). Signs of allergy include skin rash, itching, shortness of breath, and/or swollen face;

- if the packaging is torn or shows signs of being tampered with;
- if the tablets do not look right;
- to treat any other complaints unless your doctor says it is safe to do so.

Before you start to take it

Risperidone generichealth should be used with caution in some patients.

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

- irregular heart rhythm, abnormalities in electrical activity of the heart, high or low blood pressure, or you've had a heart attack or stroke in the past;
- unusual excessive sweating or diarrhoea, dehydration or problems with your body temperature regulation;
- kidney or liver problems;
- you are prone to dizziness when standing up from lying or sitting position;
- Parkinson's disease (a progressive movement and thinking disorder that tends to affect older people);
- dementia or Lewy body dementia; Older people suffering dementia may be at increased risk of stroke or death with Risperidone generichealth;
- sugar diabetes;
- unusual thirst, tiredness, blurred vision, upset stomach or need to urinate - common signs of high blood sugars;
- epilepsy, seizures or fits;
- continuous and/or painful erections (called 'priapism');
- involuntary movements or unusual restlessness or difficulty sitting still;
- suicidal thoughts or past suicide attempts;
- low blood potassium levels (hypokalaemia);
- breast cancer;
- cancer of the pituitary gland.;
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the tongue, face, mouth, jaw, arms and legs);
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines that causes sudden increase in body temperature, very fast heartbeat, extremely high or low blood pressure and severe muscle stiffness or fits);
- blood clots; Tell your doctor if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs can occur with risperidone. Blood clots in the lungs can result in death;
- low white blood cell count. If you have low numbers of some white blood cells, your risk of contracting an infection or developing a fever is increased with Risperidone generichealth.

Tell your doctor if

- **you have any eye surgery planned.** Your doctor will need to assess whether you are at risk of a surgical complication (called 'Intraoperative Floppy Iris

Syndrome'). You may be recommended to stop your Risperidone generichealth temporarily prior to your eye surgery.

- **you are pregnant or planning to become pregnant.**

Your doctor will advise you whether you should take Risperidone generichealth. Newborn babies of mother taking Risperidone generichealth in their last trimester may be at risk of having difficulty feeding or breathing, shaking, muscle stiffness and/or weakness, sleepiness or agitation.

- **you are breast-feeding.**

As Risperidone generichealth is excreted in breast milk, it is recommended that you do not breast-feed while taking the medicine.

- **you will be in a hot environment or do a lot of vigorous exercise.**

Risperidone generichealth may make you sweat less, causing your body to overheat.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Risperidone generichealth.

Taking other medicines

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

In particular, tell your doctor if you are taking:

- sleeping tablets, tranquillisers, strong pain-killers, certain allergy medicines called antihistamines, certain antidepressants and alcohol;
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate);
- medicines used to treat bacterial infections such as rifampicin;
- medicines to treat fungal infections such as itraconazole and ketoconazole;
- medicines to treat HIV/AIDS, such as ritonavir and tipranavir;
- other medicines to treat mental illness or psychotic conditions;
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder such as fluoxetine, paroxetine, sertraline and fluvoxamine;
- medicines for your heart or blood pressure;
- verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm;
- frusemide, a medicine used to treat high blood pressure and fluid build-up. There is an increased risk of side effects or death in older people if frusemide is also taken with Risperidone generichealth.
- medicines to treat epilepsy;
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face);
- medicines to treat Parkinson's disease or a tremor.

Taking it for the first time

At the start of treatment, you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

How to take Risperidone generichealth

How much to take

Your doctor will decide the dose suitable for you.

Follow your doctor's instructions carefully and do not change or stop the required dosage without consulting your doctor first.

Important note: never take more tablets than your doctor tells you to take.

Risperidone generichealth cannot be recommended for use in children with schizophrenia under 15 years at the present time as there is little experience with the product in this group.

For Schizophrenia and Related Psychoses

The usual starting dose of Risperidone generichealth is 1 mg twice a day. This will be gradually increased by your doctor to suit your needs.

From then on, the dose can be taken once a day or twice a day according to your doctor's instructions.

For Elderly Patients with Schizophrenia or Related Psychoses

For older patients a starting dose of 0.5 mg (half a 1 mg tablet) twice a day (in the morning and in the evening is usual). This may be gradually increased by your doctor to suit your needs.

Patients with impaired kidney and liver function.

If you have kidney or liver disease a starting dose of 0.5 mg (half a 1 mg tablet) twice a day (in the morning and in the evening) is usual. This may be gradually increased by your doctor to suit your needs.

For acute mania

The recommended starting dose is 2 mg once a day. This may be gradually increased by your doctor to suit your needs.

Your doctor may decide you should take another medicine called a mood stabiliser as well as Risperidone generichealth.

For Behavioural Problems in People with Dementia

The usual starting dose is 0.25 mg twice daily. This may be gradually increased by your doctor to suit your needs.

For Disruptive Behaviour Disorders in Adults and Children

For people who weigh 50 kg or more, the usual starting dose is 0.5 mg (half a 1 mg tablet) once a day. This may be gradually increased by your doctor to suit your needs.

For people who weigh less than 50 kg, the usual starting dose is 0.25 mg once a day. This may be gradually increased by your doctor to suit your needs.

Your doctor will advise you on how much Risperidone generichealth you need.

Risperidone generichealth cannot be recommended for use in children with disruptive behaviour disorders under 5 years

at the present time as there is little experience with the product in this group.

For Behavioural Disorders Associated with Autism in Children and Adolescents

For people weighing less than 20 kg the usual starting dose is 0.25 mg. This may be gradually increased by your doctor to suit your needs.

For people weighing 20 kg or more the usual starting dose is 0.5 mg. This may be gradually increased by your doctor to suit your needs.

Your doctor will advise you on how much Risperidone generichealth you need.

How to take it

Risperidone generichealth should be swallowed with water or other liquid.

It is very important that you take the correct amount of Risperidone generichealth, but this will vary from person to person. Your doctor will adjust the number and strength of the tablets until the desired effect is obtained.

When to take it

Risperidone generichealth may be taken as a single dose, once a day or it may be taken in divided doses twice a day (in the morning and in the evening).

You may take Risperidone generichealth either with or between meals.

How long to take it

Continue taking the tablets for as long as your doctor tells you.

Risperidone generichealth helps control your condition, but does not cure it. Therefore, you must take Risperidone generichealth every day.

Do not stop taking it unless your doctor tells you to – even if you feel better.

If you forget to take it

If you forget to take Risperidone generichealth, take the missed dose as soon as you remember instead of your next dose. Then continue taking it as you would normally.

Do not take a double dose to make up for the one you missed. If you forget to take Risperidone generichealth for a number of days or more, tell your doctor before starting your medicine again.

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

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Risperidone generichealth. Do this even if there are no signs of discomfort or poisoning.

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

While you are taking Risperidone generichealth

Things you must do

Always follow your doctor's instructions carefully, and seek your doctor's advice before changing or stopping treatment. Your doctor will be happy to discuss any questions you may have with your treatment.

Try to eat a moderate diet.

Risperidone generichealth can cause weight gain.

Tell all doctors, dentists, and pharmacists who are treating you that you are taking Risperidone generichealth.

Tell your doctor if you are not pregnant or planning to become pregnant.

If you are pre-menopausal, tell your doctor if you do not have a period for more than six months while taking Risperidone generichealth, even if you are not pregnant.

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

These may be symptoms of a condition called Tardive Dyskinesia, which can develop in people taking antipsychotic medicines, including Risperidone generichealth. This condition is more likely to occur during longer term treatment and in older women. In very rare cases, these symptoms may be permanent. However, if detected early, these symptoms are usually reversible.

Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water.

Things you must not do

Do not drink alcohol.

Risperidone generichealth can increase the effects of alcohol.

Things to be careful of

Ask your doctor or pharmacist before taking any other medicines.

Risperidone generichealth can increase the effects of medicines which slow your reactions. Always ask your doctor or pharmacist before taking other medicines, including herbal treatments and medicines that can be bought in a pharmacy or supermarket.

Avoid driving or operating machinery until you are sure Risperidone generichealth does not affect your alertness.

Risperidone generichealth may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to Risperidone generichealth before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

If the medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.

Avoid excessive eating.

There is a possibility of weight gain when taking Risperidone generichealth. Your doctor may monitor your body weight or recommend strategies to assist with weight management.

Side effects

All medicines can have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

All medicines can have side effects. You may need medical treatment if you get some of the side effects.

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

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

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

- **difficulty thinking, working or carrying out your usual daily activities because of:**
 - headache;
 - trembling, muscle weakness, unsteadiness on your feet, lack of coordination or slow, shuffling walk (symptoms of Parkinsonism);
 - lack of energy, drowsiness, or excessive sleeping during the day, sleeplessness or difficulty in concentrating;
 - difficulty speaking;
 - blurred vision;
 - fainting;
 - dizziness;
 - any problems with confusion or unsteadiness;
 - pains in parts of your body, eg. in the neck, back, ear, hands or feet;
 - falling.
- **muscle, joint, nerve or movement changes such as:**
 - shaking or trembling;
 - fatigue or weakness;
 - muscle stiffness;
 - restlessness in the legs or difficulty sitting still;
 - uncontrolled muscle spasms, twitching, jerky or writhing movements;
 - muscle aches or pain.
 - joint swelling or pain;
 - walking abnormally or with difficulty;
 - abnormal posture, such as rigid body movements and persistent abnormal positions of the body.
- **behavioural changes such as:**
 - irritability or agitation;
 - unusual anxiety or nervousness;
- **other changes such as:**
 - cold or "flu-like" symptoms eg. cough, blocked or runny nose, sneezing, sore throat;
 - feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell (signs of sinusitis);
 - tiredness, headaches, being short of breath when exercising, dizziness and looking pale (signs of decreased red blood cells);
 - fever, chills, shortness of breath, cough, phlegm and occasionally blood (signs of pneumonia);
 - nosebleeds;
 - discharge with itching of the eyes and crusty eyelids;
 - unexplained weight gain;

- unexplained increase or decrease in appetite;
 - indigestion, stomach discomfort or pain, diarrhoea or constipation;
 - nausea or vomiting;
 - dry mouth or excessive thirst;
 - drooling;
 - difficulty swallowing;
 - acne;
 - dry skin;
 - rash, red skin or itchy skin;
 - thickening of the skin resulting in warts, corns, calluses;
 - skin infection;
 - swelling of any part of your body, eg. hands, ankles or feet;
 - inability to or feeling burning pain when passing urine;
 - some loss of bladder control;
 - bedwetting;
 - frequent daytime urination in children;
 - sexual function disturbances - problems with ejaculation;
 - breast abnormalities – breast discomfort or swelling or unusual secretion of breast milk;
 - missed or irregular menstrual periods;
 - dizziness on standing up, especially when getting up from a sitting or lying down position;
 - shortness of breath;
 - chest pain or discomfort;
 - an increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown.
- These can only be detected by blood tests that your doctor may ask to be done.

These are mild side effects of Risperidone generichealth but may require medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- **signs of heart or blood pressure problems including:**
 - fainting, blurry vision, light-headedness or dizziness particularly on standing that persists despite sitting or lying down again;
 - very fast heart rate, slowed heart rate, heart rhythm irregularities;
- **signs of lung problems including:**
 - sudden shortness of breath, trouble breathing, wheezing or gasping when you breathe, light-headedness or dizziness.
- **signs of high blood sugar or diabetes such as:**
 - unusual thirst, tiredness, upset stomach or need to urinate more often than usual.
- **body temperature changes such as:**
 - fever;
 - unexplained high body temperature, excessive sweating or rapid breathing;
 - severe muscle stiffness or fits.
- **involuntary movements of the tongue, face, mouth, jaw, arms, legs or trunk.**
- **severe or life-threatening rash with blisters and peeling skin that may start in and around the mouth, nose, eyes, and genitals and spread to other areas of the body (Stevens-Johnson syndrome or toxic epidermal necrolysis).**

- **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 them, you may have had a serious allergic reaction to Risperidone generichealth.
- **sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes).**

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

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 taking Risperidone generichealth

Storage

Keep Risperidone generichealth in a dry place where the temperature stays below 25°C.

Do not store it or any medicines in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Do not use Risperidone generichealth beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly. Medicines cannot be stored indefinitely.

Do not use Risperidone generichealth if the appearance of the tablets has changed.

Disposal

If your doctor tells you to stop taking Risperidone generichealth or if it has passed the expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Risperidone generichealth 1 mg are white, capsule-shaped, biconvex film-coated tablets, debossed with '1' on one side and scoreline on the other side.

Risperidone generichealth 2 mg are orange, capsule-shaped, biconvex film-coated tablets, debossed with '2' on one side and scoreline on the other side.

Risperidone generichealth 3 mg are dark yellow, capsule-shaped, biconvex film-coated tablets, debossed with '3' on one side and scoreline on the other side.

Risperidone generichealth 4 mg are red brown, capsule-shaped, biconvex film-coated tablets, debossed with '4' on one side and scoreline on the other side.

Ingredients

Active ingredients

Risperidone generichealth tablet contains 1 mg, 2 mg, 3 mg or 4 mg risperidone.

Other ingredients

- lactose monohydrate;
- pregelatinised maize starch;
- microcrystalline cellulose;
- magnesium stearate;
- colloidal anhydrous silica;
- sodium lauryl sulphate;
- purified talc;
- OPADRY complete film coating system 03H58880 White (1 mg tablet only);
- OPADRY complete film coating system 03H53653 Orange (2 mg tablets only);
- OPADRY complete film coating system 03H52035 Yellow (3 mg tablets only);
- OPADRY complete film coating system 03H86621 Brown (4 mg tablets only).

Australian Registration Numbers

Risperidone generichealth 1 mg: AUST R 139801.

Risperidone generichealth 2 mg: AUST R 139813.

Risperidone generichealth 3 mg: AUST R 139821.

Risperidone generichealth 4 mg: AUST R 139824.

Sponsor

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