

RISPERIDONE GENERICHEALTH

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Risperidone generichealth.

It does not contain all 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.

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

What Risperidone generichealth is used for

Risperidone generichealth is used to treat symptoms of schizophrenia and other types of related psychoses.

These are disorders related to thought, feeling and/or action.

Risperidone generichealth may be taken for both sudden (acute) and long-lasting (chronic) schizophrenia.

Risperidone generichealth is also used for the 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.

Risperidone generichealth is also used to treat behavioural problems in patients with a decline in mental ability (dementia). These problems include: aggression through words or action, morbid suspiciousness, agitation or wandering

Risperidone generichealth can be used to treat 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.

Risperidone generichealth can also be used to treat behavioural symptoms of autism in children and adolescents

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

Risperidone generichealth has been approved for the uses mentioned above. However, your doctor may prescribe this medicine for another use. 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 (signs of allergy include skin rash, itching, shortness of breath, and/or swollen face - see the last section of this leaflet for a list of ingredients)

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 ever had allergies to:

- heart or blood vessel diseases, including low blood pressure
- dehydration
- kidney or liver problems
- Parkinson's disease
- dementia or Lewy body dementia
- epilepsy
- breast cancer
- disease of the pituitary gland
- diabetes

- disease of the blood vessels of the brain including stroke
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs)
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)

Tell your doctor if

- you are pregnant or are planning to become pregnant. Your doctor will advise you whether or not you should take Risperidone generichealth .
- you are breast feeding. Risperidone generichealth is excreted in breast milk. It is recommended that you do not breast-feed while taking Risperidone generichealth.

Other medicines and alcohol

Risperidone generichealth can increase the effect of alcohol and other medicines which slow your reactions.

You should not drink alcohol while taking Risperidone generichealth .

In studies in elderly patients with dementia where risperidone tablets were compared with a dummy pill, the death rate was 3.1% with the dummy pill and slightly higher at 4% with risperidone tablets. Taking risperidone with frusemide, a drug which is used to treat high blood pressure, or to treat swelling of parts of the body caused by the build-up of too much fluid, contributed to this difference, so this combination may be harmful. Tell your doctor if you are taking frusemide (trade names LASIX, UREMIDE, UREX, FRUSID, or FRUSEHEXAL).

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
- tranquilisers
- pain-killers
- antihistamines
- medicines to treat Parkinson's disease or a tremor
- medicines to treat epilepsy
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder. For example fluoxetine and paroxetine may increase the level of risperidone in your blood. So tell your doctor if you start and/or stop taking fluoxetine or paroxetine.
- diuretics
- medicines for your heart or blood pressure
- medicines to treat pre-menstrual dysphoric disorder
- other medicines to treat mental illness or psychotic conditions
- medicines to relieve severe nausea and vomiting.

Elderly People

Elderly people should take less Risperidone generichealth than are prescribed for other adults (see "How to take Risperidone generichealth").

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 to take it

Risperidone generichealth is not available in a 0.25 mg strength. Other brands are available if this dose strength is required.

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)

Risperidone generichealth should be swallowed with water or other liquid. You may take Risperidone generichealth either with or between meals.

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.

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

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 long-term treatment, 4 to 6 mg per day is usually sufficient but your doctor will determine the dose most suitable for you.

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

The effects of high doses are not yet known. Please double check with your doctor if your doctor prescribes more than 5 mg twice a day.

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 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). The dose may be increased by 0.5 mg twice daily to 1 to 2 mg twice a day (in the morning and in the evening).

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. The dose may be increased by 0.5 mg twice daily to 1 to 2 mg twice a day (in the morning and in the evening).

For acute mania

The recommended starting dose is 2mg once a day. This dose can be adjusted by dose increases of 1mg when needed every 24 hours. Most people feel better with doses between 2mg and 6mg a day. Your doctor may decide you should take another drug 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.

From then on the dose can be taken once a day or twice a day according to your doctor's instructions. For long-term treatment, 1 mg daily is the usual dose but your doctor will determine the dose most suitable for you.

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. The dose may be increased by 0.5 mg once every two days, to the usual dose of 0.5 to 1.5 mg once a day.

For people who weigh less than 50 kg, the usual starting dose is 0.25 mg once a day. The dose may be increased by 0.25 mg once every two days, to the usual dose of 0.25 to 0.75 mg once a day.

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 Autism in Children and Adolescents

For people weighing 20kg or less the usual starting dose is 0.25mg. On day 4 this dose can be increased to 0.5mg.

For people weighing more than 20kg the usual starting dose is 0.5mg. On day 4 this dose can be increased to 1.0mg.

Response should be assessed at day 14. Only in patients not achieving

sufficient clinical response should additional dose increases be considered. Your doctor will advise you on how much Risperidone generichealth you need. When trialled, the maximum dose in patients with autism did not exceed 1.5mg/day in patients <20kg, 2.5mg in patients >20kg or 3.5mg in patients >45kg

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 5 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 using 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.

Pre-menopausal women should tell their doctor if they do not have a

period for more than six months while taking Risperidone generichealth.

Things to be careful of

Do not drink alcohol. Risperidone generichealth can increase the effects of alcohol.

Ask your doctor 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. These include herbal treatments and those bought in a pharmacy or supermarket.

Be careful driving or operating machinery until you know how Risperidone generichealth affects you. Risperidone generichealth may cause dizziness, drowsiness 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.

Avoid excessive eating, as there is a possibility of weight gain when taking Risperidone generichealth.

Side effects

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. Risperidone generichealth is generally well-tolerated and side effects are often hard to distinguish from the disease symptoms. You may need medical treatment if you get some of the side effects. **Tell your doctor as soon as possible if you do not feel well while you are using Risperidone generichealth.**

Below is a list of possible side effects you could get while taking risperidone tablets:

- Sleeplessness
- Agitation
- Anxiety
- Headache
- Trembling
- excessive saliva
- muscle stiffness
- restlessness in the legs
- fall in blood pressure, particularly on standing. This will be apparent to you as light-headedness or dizziness that passes after a few

seconds or after sitting down again.

- fast heart rate

Although these effects are generally not harmful, contact your doctor if they bother you too much.

The following may occur less often:

- drowsiness
- tiredness
- difficulty in concentrating
- somnolence, usually mild and short lasting, may occur more often in children than in adults
- blurred vision
- dizziness
- indigestion
- nausea
- abdominal pain, constipation
- sexual function disturbances
- some loss of bladder control
- blocked nose
- weight gain
- excessive thirst

After taking Risperidone generichealth for a long time, twitching of the tongue, face, mouth and jaws can occur. Should this happen contact your doctor. In the early stages of treatment, in some people, blood pressure may decrease slightly and the heart beat increase resulting in dizziness. This usually goes away after a few days. (See "Taking it for the first time"). After taking Risperidone generichealth for a long time, some women may experience breast enlargement or get a discharge from the breasts. They may also experience irregular or heavy periods or absence of their periods. In men, breasts may enlarge slightly. The following may occur rarely:

- Oversensitivity (allergy). (See "When you must not use it").

In extremely rare cases, significant changes in body temperature may occur. This rise or fall in temperature is caused by a combination of several factors such as extreme cold or heat. Call your doctor if this happens.

In elderly patients with dementia, sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke have been seen. If any of these should occur, even if for a short period of time, seek medical attention right away.

In very rare cases, high blood sugar has been reported. The symptoms of high blood sugar may be the need to urinate more often or feeling thirsty all the time.

Contact your doctor if you experience any of these symptoms

IMPORTANT: If you experience high fever, stiff muscles, fast breathing, abnormal sweating or decreased mental alertness, contact your doctor immediately. Your body may not be reacting properly to the medicine.

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

After using 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

Once you have finished using Risperidone generichealth, ask your pharmacist what to do with any unused medicine.

Product description

What it looks like

Risperidone generichealth is available in four different strengths.

Risperidone generichealth 1 mg - white, capsule-shaped, biconvex film-coated tablets, debossed with '1' on

one side and scoreline on the other side.

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

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

Risperidone generichealth 4 mg - 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 1 mg contains 1 mg risperidone

Risperidone generichealth 2 mg contains 2 mg risperidone

Risperidone generichealth 3 mg contains 3 mg risperidone

Risperidone generichealth 4 mg contains 4 mg risperidone

Inactive Ingredients:

The 1 mg tablets contain:

lactose
pregelatinised maize starch
microcrystalline cellulose
magnesium stearate
colloidal anhydrous silica
sodium lauryl sulphate
purified talc
hypromellose(E464),
titanium dioxide(E171)
propylene glycol(E1520).

The 2 mg tablets contain:

lactose
pregelatinised maize starch
microcrystalline cellulose
magnesium stearate
colloidal anhydrous silica
sodium lauryl sulphate
purified talc
hypromellose (E464)
titanium dioxide (E171)
propylene glycol (E1520)
FD and C yellow # 6/sunset yellow
FCF
Aluminum lake (E110).

The 3mg tablets contain:

lactose
pregelatinised maize starch
microcrystalline cellulose
magnesium stearate
colloidal anhydrous silica
sodium lauryl sulphate
purified talc
hypromellose (E464)
iron oxide yellow (E172)
titanium dioxide (E171)
propylene glycol (E1520).

The 4mg tablets contain:

lactose
pregelatinised maize starch
microcrystalline cellulose
magnesium stearate
colloidal anhydrous silica
sodium lauryl sulphate
purified talc
hypromellose (E464)
titanium dioxide(E171)
propylene glycol (E1520)
iron oxide red (E172)

Risperidone generichealth does not contain gluten, sucrose, tartrazine or any other azo dyes

Sponsor

Generic Health Pty Ltd
Suite 1, Level 1
1175 Toorak Road
Camberwell Victoria 3124

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

This leaflet was prepared 27th August 2008