

APO-Risperidone Tablets

Contains the active ingredient risperidone

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about risperidone. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Risperidone. It contains the active ingredient risperidone.

It is used for:

- Symptoms of schizophrenia and other types of related psychoses in adults, adolescents and children over 15 years of age. These are conditions related to thoughts, feelings and/or actions. Risperidone may be taken for both sudden (acute) and long-lasting (chronic) schizophrenia.
- Acute mania associated with Bipolar 1 Disorder (short term treatment). People with this condition may have symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgment including disruptive or aggressive behaviours.
- Behavioural problems in patients with a decline in mental ability (dementia). These problems include: aggression through words or action, morbid suspiciousness, agitation or wandering.

- Conduct and other disruptive disorders in adults, adolescents and children over 5 years old who are intellectually disabled and who show destructive behaviours such as aggression, impulsiveness and self-injury.
- Certain behaviours seen in children and adolescents with autism.

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

Your doctor may have prescribed this medicine for another reason.

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

There is no evidence that this medicine is addictive.

How it works

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

There is no evidence that this medicine is addictive.

Before you take this medicine

When you must not use it

Do not use this medicine if:

- **You have had an allergic reaction 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, throat or other parts of the body; rash, itching or hives on the skin.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- heart or blood vessel problems including low or high blood pressure
- disease of the blood vessels of the brain including stroke
- dehydration
- kidney or liver problems
- Parkinson's disease
- dementia or Lewy Body dementia
- epilepsy or seizures
- low volume of blood in your body (hypovolaemia) - seen by cold hands and feet, light-headedness, infrequent urination, increased heart rate, and weakness
- breast cancer
- disease of the pituitary gland
- diabetes, high or low blood sugar (you may need to monitor your blood glucose levels closely)
- tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or

jerked 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).
- 3. **You are currently pregnant or you plan to become pregnant.** Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
- 4. **You are currently breastfeeding or you plan to breastfeed.**
- 5. **You are planning to have surgery or an anaesthetic.**
- 6. **You are currently receiving or are planning to receive dental treatment.**

If you have not told your doctor about any of the above, tell them before you use this medicine.

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.

Some medicines may interact with risperidone. These include:

- sleeping tablets, tranquillisers, pain-killers or antihistamines which may make you drowsy
- medicines to treat Parkinson's disease or a tremor
- carbamazepine a medicine used to treat epilepsy and other disorders
- medicines to treat depression, panic disorder, anxiety, obsessive-compulsive disorder or premenstrual dysphoric disorder, such as tricyclic antidepressants and selective serotonin reuptake inhibitors (SSRIs). For e.g. fluoxetine and paroxetine may increase the level of risperidone in your blood. Tell your doctor if you start and/or stop taking fluoxetine or paroxetine
- other medicines to treat mental illness or psychotic conditions

- diuretics. 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, may increase the risk of side effects or death in elderly people. Tell your doctor if you are taking frusemide (e.g. Lasix, Uremide, Urex, Frusid, Frusehexal).
- medicines for your heart or blood pressure. Taking risperidone with medicines which help heart problems or lower your blood pressure may make your blood pressure even lower
- medicines to relieve severe nausea and vomiting
- cimetidine and ranitidine, used for treating stomach ulcers or excess acid
- medicines which have an effect on the heart called QT prolongation
- medicines which affect the liver so that more of an enzyme called CYP3A4 is produced.
- medicines which treat fungal infections. For example itraconazole may elevate the level of risperidone in your blood. Tell your doctor if you start and/or stop taking itraconazole.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with risperidone.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist carefully and do not use more than the recommended dose.

Their instructions may be different to the information in this leaflet.

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

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.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

These symptoms should go away after a few days. Tell your doctor if they continue or worry you.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Risperidone 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).

It is very important that you take the correct amount of risperidone, 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.

For Schizophrenia and Related Psychoses in Adults and Children over 15:

The usual starting dose of risperidone 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 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 in Elderly Patients:

For older patients a starting dose of 0.5 mg (0.5 mg tablet or 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 Schizophrenia or Related Psychoses who have Impaired Kidney or Liver Function:

If you have kidney or liver disease a starting dose of 0.5 mg (0.5 mg tablet or 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 in Patients with Bipolar 1 Disorder:

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

For Behavioural Problems in People with Dementia:

The usual starting dose is 0.25 mg (half a 0.5 mg tablet) 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 Conduct and other Disruptive Disorders in adults, adolescents and children over 5 years old who are intellectually disabled:

For people who weigh 50 kg or more, the usual starting dose is 0.5 mg (0.5 mg tablet or 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 (half a 0.5 mg tablet) 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 you need.

Risperidone cannot be recommended for use in children under 5 years or age with disruptive behaviour disorders 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 (half a 0.5 mg tablet). On day 4, this dose can be increased to 0.5 mg.

For people weighing 20 kg or more the usual starting dose is 0.5 mg (0.5 mg tablet or half a 1 mg tablet). On day 4, this dose can be increased to 1 mg.

After 14 days, the doctor should check that the tablets are working. The doctor will say whether a bigger dose is needed if the tablets do not seem to be having the desired effect. Your doctor will advise you on how much risperidone you need.

In clinical trials, people with autism weighing less than 20 kg did not need more than 1.5 mg/day. People weighing over 20 kg did not need more than 2.5 mg of risperidone a day, and people weighing over 45 kg did not need more than 3.5 mg a day.

If you feel sleepy, then the doctor may split up your daily dose so that you take half of it in the morning and half in the evening.

How to take it

Risperidone tablets should be swallowed with a glass of water or other liquid.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it

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

Make sure you have enough to last over weekends and holidays.

Do not stop taking this medicine without first talking to your doctor.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much risperidone, you may experience drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, increased heart rate, and/or very low blood pressure causing fainting or unconsciousness.

While you are taking this medicine

Things you must do

- **If you become pregnant while you are using this medicine, tell your doctor.**
- **Tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.**
- **If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using this medicine.**
- **If you are going to have surgery, inform your doctor and tell the surgeon or anaesthetist that you are using this medicine.**
- Go to your doctor regularly for a check-up. Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.
- If a child is taking risperidone, tell the doctor if they do not seem to be developing normally.
- **Try to eat a moderate diet.** Risperidone 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.

When you begin to take risperidone, you may feel light-headed, dizzy or faint when getting out of bed or standing up. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

If this problem gets worse or continues, talk to your doctor.

Things you must not do

Do not:

- Drink alcohol. Risperidone can increase the effects of alcohol.
- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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

Avoid excessive eating.

There is a possibility of weight gain when taking risperidone

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

Your doctor will decide whether any change in your treatment is needed.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. 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 if you notice any of the following side effects and they worry you:

- problems sleeping

- headache
- trembling agitation, anxiety
- dry mouth; dry, swollen or cracked lips
- increased or decreased appetite
- excessive saliva or drooling
- nausea, vomiting
- indigestion
- abdominal pain, diarrhoea, constipation
- restlessness in the legs
- weight gain
- hair loss, dandruff, rash or other skin disorders, or nail infection
- blocked nose, sinusitis, nose bleed
- missed, irregular or heavy periods
- unusual secretion of breast milk
- breast swelling (men or women)
- sexual function disturbances
- 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.

This list includes the more common side effects. Mostly, these are mild.

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

These may be serious side effects. You may need medical attention.

Most of these side effects are rare.

- drowsiness, tiredness, listlessness, difficulty in concentrating, excessive sleepiness, slow reactions
- dizziness
- confusion, nervousness
- breathing problems, cough
- flushing
- muscle or joint pain, swelling, stiffness or weakness
- ear pain or ringing in the ears (tinnitus)
- fever or infection of the chest, throat, ears, sinuses, tonsils or urinary tract
- an increased tendency to get infections or sore throats
- problems swallowing

- some loss of bladder or bowel control
- high blood sugar
The symptoms of high blood sugar may be the need to urinate more often or feeling thirsty all the time
- increased blood cholesterol
- uncontrollable movements of the tongue, face, mouth and jaws, arms legs or trunk
- dark coloured urine
- swelling of the ankles, feet or legs due to fluid build up
- uncoordinated movements, feeling unbalanced
- liver problems, yellow skin or eyes
- eye problems (dryness, swelling, itching, infection, problems seeing, blurred vision).

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

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

- significant changes in body temperature (e.g. very high temperature or chills)
- high fever, stiff muscles, fast breathing, abnormal sweating or decreased mental alertness. Your body may not be reacting properly to the medicine
- fast or slow or irregular or thumping heart beat
- chest pain
- loss of consciousness or fainting
- sudden weakness or numbness of the face, arms or legs, especially on one side, or slurred speech (symptoms of stroke or mini-stroke)
- in men, a prolonged and painful erection.

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

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of

your health, even if you think the problems are not associated with this medicine and are not referred to in this leaflet.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Allergic reactions

If you think you are having an allergic reaction to risperidone, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your tablets in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Risperidone looks like

APO-Risperidone 0.5 mg tablets:

Brownish-red, capsule-shaped film-coated tablets. Engraved "APO" on one side, "RI" score ".5" on the other side.

Blister pack of 20 tablets.

Bottle of 20 tablets.

APO-Risperidone 1 mg tablets:

White, capsule-shaped film-coated tablets. Engraved "APO" on one side, "RI" score "1" on the other side.

Blister pack of 60 tablets.

Bottle of 60 tablets.

APO-Risperidone 2 mg tablets:

Light orange, capsule-shaped film-coated tablets. Engraved "APO" on one side, "RI" score "2" on the other side.

Blister pack of 60 tablets.

Bottle of 60 tablets.

APO-Risperidone 3 mg tablets:

Beige, capsule-shaped film-coated tablets. Engraved "APO" on one side, "RI" score "3" on the other side.

Blister pack of 60 tablets.

Bottle of 60 tablets.

APO-Risperidone 4 mg tablets:

Light green, capsule-shaped film-coated tablets. Engraved "APO" on one side, "RI" score "4" on the other side.

Blister pack of 60 tablets.

Bottle of 60 tablets.

*Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 0.5 mg, 1 mg, 2 mg, 3 mg or 4 mg of risperidone as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- cellulose microcrystalline
- maize starch
- magnesium stearate

- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- iron oxide red (0.5 mg)
- sunset yellow FCF aluminium lake (2 mg)
- iron oxide yellow (3 mg and 4 mg)
- indigo carmine aluminium lake (4 mg).

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Risperidone 0.5 mg tablets

Blister pack AUST R 127606.

APO-Risperidone 0.5 mg tablets

Bottle AUST R 127607.

APO-Risperidone 1 mg tablets

Blister pack AUST R 127608.

APO-Risperidone 1 mg tablets

Bottle AUST R 127609.

APO-Risperidone 2 mg tablets

Blister pack AUST R 127610.

APO-Risperidone 2 mg tablets

Bottle AUST R 127611.

APO-Risperidone 3 mg tablets

Blister pack AUST R 127612.

APO-Risperidone 3 mg tablets

Bottle AUST R 127613.

APO-Risperidone 4 mg tablets

Blister pack AUST R 127615.

APO-Risperidone 4 mg tablets

Bottle AUST R 127617.

Sponsor

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