

Consumer Medicine Information**WHAT IS IN THIS LEAFLET**

This leaflet answers some common questions about Risperidone Sandoz.

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 this medicine 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 RISPERIDONE SANDOZ IS USED FOR

Risperidone Sandoz contains the active ingredient risperidone.

Risperidone 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. Symptoms of this condition include 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 (older than 5 years), adolescents and adults who are intellectually disabled.
- Treatment of behavioural symptoms of autism in children and adolescents.

This medicine helps to correct a chemical imbalance in the brain associated with the conditions mentioned above.

Ask your doctor if you have any questions about why Risperidone Sandoz was prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that Risperidone Sandoz is addictive.

BEFORE YOU TAKE RISPERIDONE SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- risperidone, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines, especially if they are in the same drug class as risperidone.

Some of the 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 take this medicine 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 ever had heart or blood vessel problems, including high or low blood pressure.

Low blood pressure can result from using Risperidone Sandoz together with medications to treat high blood pressure. So, if you need to use both Risperidone Sandoz and medications to reduce blood pressure, consult your doctor. Risperidone Sandoz should be used with caution, and only after consultation with your doctor, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if using medications that can change the heart's electrical activity.

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

- diseases of the blood vessels of the brain, including stroke
- 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
- dementia or Lewy body dementia. Older people suffering dementia may be at increased risk of stroke or death with risperidone
- 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

- disease of the pituitary gland
- diabetes
- 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 with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- 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 have been seen in patients taking risperidone. Blood clots in the lungs can be fatal.
- 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

Tell your doctor if you have an eye surgery planned.

Your doctor will need to assess whether you are at risk of a surgical complication called intraoperative iris syndrome. You may be recommended to stop your risperidone temporarily prior to your eye surgery.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Shaking, muscle stiffness and difficulty in feeding, all of which are reversible, may occur in newborns, if the mother takes this medicine in the last trimester of her pregnancy.

Tell your doctor if you are breastfeeding.

The active ingredient risperidone is excreted in breast milk, thus breastfeeding is not recommended while taking this medicine.

If you will be in a hot environment or do a lot of vigorous exercise. Risperidone may make you sweat less, causing your body to overheat.

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

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.

Ask your doctor or pharmacist before taking any other medicines. Risperidone Sandoz can increase the effects of medicines which slow your reactions. These include herbal treatments.

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

- Diuretics (e.g. frusemide), medicines used to treat high blood pressure or swelling of parts of the body caused by the build-up of too much fluid. There is an increased risk of side effects or death in elderly people if frusemide is taken with Risperidone Sandoz.
- Other medicines for your heart or blood pressure.

- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- Sleeping tablets, tranquillisers, pain-killers, antihistamines, certain antidepressants and alcohol.
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate)
- Antibiotics like rifampicin
- Medicines used to treat epilepsy or trigeminal neuralgia (severe pain attacks in the face). For example, carbamazepine
- Anti-fungals like itraconazole and ketoconazole
- Medicines to treat HIV/AIDS, such as ritonavir and tipranavir
- Medicines used to treat Parkinson's Disease or a tremor.
- Medicines used to treat depression, panic disorder, anxiety or obsessive-compulsive disorder (e.g. fluoxetine or paroxetine). These medicines may increase the level of risperidone in your blood. Tell your doctor if you start or stop taking fluoxetine or paroxetine.
- Other medicines used to treat mental illness or psychotic conditions.

These medicines may be affected by Risperidone Sandoz 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.

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 SANDOZ

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, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide the dose suitable for you.

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.

The maximum daily dose is 5 milligrams taken twice a day. Check with your doctor if more than this has been prescribed. The effects of high doses are not yet known. This medicine 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 Sandoz is 1mg 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 milligrams per day is usually sufficient but your doctor will determine the dose most suitable for you.

For elderly patients with schizophrenia or related psychoses

For older patients a starting dose of 0.5mg twice a day (in the morning and in the evening) is usual. The dose may be increased by 0.5mg twice daily to 1mg to 2mg twice a day (in the morning and in the evening).

For patients with impaired kidney and liver function

If you have kidney or liver disease a starting dose of 0.5mg twice a day (in the morning and in the evening) is usual. The dose may be increased by 0.5mg twice daily to 1 to 2mg 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 every 24 hours, when needed. Most people feel better with doses between 2mg and 6mg a day. Your doctor may decide that you should take another drug called a mood stabiliser as well as Risperidone Sandoz.

For behavioural problems in people with dementia

The usual starting dose is 0.25mg (a half of a 0.5mg 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, 1mg 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 50kg or more, the usual starting dose is 0.5mg once a day. The dose may be increased by 0.5mg once every two days, to the usual dose of 0.5mg to 1.5mg once a day.

For people who weigh less than 50kg, the usual starting dose is 0.25mg once a day (a half of a 0.5mg tablet). The dose may be increased by 0.25mg once every two days, to the usual dose of 0.25mg to 0.75mg once a day.

Your doctor will advise you on how much Risperidone Sandoz you need. Risperidone Sandoz 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 20kg, the usual starting dose is 0.25mg (a half of a 0.5mg tablet). On day 4 this dose can be increased to 0.5mg.

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

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 Sandoz you need. When trialled, the maximum dose in patients with autism did not exceed 1.5mg/day in patients less than 20kg, 2.5mg in patients 20kg or more, or 3.5mg in patients more than 45kg.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

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

How to take it

Swallow the tablets with water or other liquid.

If you need to break Risperidone Sandoz, hold tablet with both hands and snap along break line.

When to take Risperidone Sandoz

This medicine 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 it either with or between meals.

How long to take Risperidone Sandoz

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

This medicine helps to control your condition, but does not cure it. Therefore you must take this medicine every day.

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

If you forget to take your dose

If you forget to take Risperidone Sandoz, 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 dose you missed.

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

If you forget to take Risperidone Sandoz 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 when to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Risperidone Sandoz. 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, excessive trembling, excessive muscle stiffness, increased heart rate, very low blood pressure causing fainting or unconsciousness.

WHILE YOU ARE TAKING RISPERIDONE SANDOZ

Things you must do

Always follow your doctor's instructions carefully and seek your doctor's advice before changing or stopping treatment.

Try to eat a moderate diet:

risperidone can cause weight gain.

If you become pregnant while taking this medicine, 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 Risperidone Sandoz.

Tell your doctor immediately if you notice any involuntary movements of the tongue, or other 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 Risperidone Sandoz. This condition is more likely to occur during long term treatment with Risperidone Sandoz, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

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

If you are about to be started on any new medicine, including herbal treatments and drugs bought in a pharmacy or supermarket, remind your doctor and pharmacist that you are taking Risperidone Sandoz.

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

Things you must not do

Do not take Risperidone Sandoz 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 change the dosage without checking with your doctor.

Do not drink alcohol.

Risperidone Sandoz can increase the effects of alcohol.

Things to be careful of

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

This medicine may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to this medicine 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 this medicine.

Your doctor may monitor your body weight or recommend strategies to assist with weight management.

SIDE EFFECTS

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

All medicines can have side effects.

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

Do not be alarmed by this list 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 if you notice any of the following and they worry you:

Difficulty thinking, working or carrying out your usual daily activities because of:

- sleeplessness
- headache
- trembling, muscle weakness, unsteadiness on your feet, lack of coordination or slow shuffling walk (symptoms of Parkinsonism)
- drowsiness, tiredness, 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

Behavioural changes such as:

- irritability or agitation
- unusual anxiety or nervousness.

Joint or movement changes such as:

- muscle stiffness
- restlessness in the legs or difficulty sitting still
- shaking or trembling
- fatigue or weakness
- 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

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 eyes and crusty eyelids

- unexplained weight gain
- unexplained increase or decrease in appetite
- indigestion, stomach discomfort or pain, nausea, abdominal pain, constipation
- 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
- bedwetting
- some loss of bladder control
- frequent daytime urination
- sexual function disturbances - problems with ejaculation
- blockage in the bowel
- unusual secretion of breast milk
- breast swelling or discomfort
- 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

These are mild side effects of Risperidone Sandoz 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:

Heart or blood pressure problems such as:

- 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.
- very fast heart rate, slowed heart rate, heart beat irregularities.

Body temperature changes such as:

- fever
- unexplained high body temperature, excessive sweating or rapid breathing

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

Involuntary movements of the tongue, face, mouth, jaws, 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

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 or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING RISPERIDONE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Risperidone Sandoz 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

Risperidone Sandoz comes in five types of tablets:

Risperidone Sandoz 0.5mg - red, oval, scored film-coated tablets.

Risperidone Sandoz 1mg - white, oval, scored film-coated tablets, coded "1" on one side.

Risperidone Sandoz 2mg - apricot, oval, scored film-coated tablets, coded "2" on one side.

Risperidone Sandoz 3mg - yellow, oval, scored film-coated tablets, coded "3" on one side.

Risperidone Sandoz 4mg - green, oval, scored film-coated tablets, coded "4" on one side.

Available in packs of 60 tablets.

Ingredients

Active Ingredient:

Risperidone Sandoz 0.5mg - 0.5mg risperidone.

Risperidone Sandoz 1mg - 1mg risperidone.

Risperidone Sandoz 2mg - 2mg risperidone.

Risperidone Sandoz 3mg - 3mg risperidone.

Risperidone Sandoz 4mg - 4mg risperidone.

Inactive ingredients:

- microcrystalline cellulose
- lactose monohydrate
- magnesium stearate
- colloidal anhydrous silica

- hypromellose
- pregelatinised maize starch (1mg, 2mg, 3mg and 4mg tablets only)
- macrogol 4000 (1mg, 2mg, 3mg and 4mg tablets only)
- croscarmellose sodium (0.5mg tablets only)
- stearic acid (0.5mg tablets only)
- titanium dioxide
- iron oxide red (0.5mg and 2mg tablets only)
- iron oxide yellow (2mg tablets only)
- quinoline yellow (3mg and 4mg tablets only)
- indigo carmine - aluminium salt (4mg tablets only).

Supplier

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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Australian Register Number(s)

Risperidone Sandoz 0.5mg film-coated tablets: AUST R 147326 (blister pack)

Risperidone Sandoz 1mg film-coated tablets: AUST R 126148 (blister pack)

Risperidone Sandoz 2mg film-coated tablets: AUST R 126158 (blister pack)

Risperidone Sandoz 3mg film-coated tablets: AUST R 126159 (blister pack)

Risperidone Sandoz 4mg film-coated tablets: AUST R 126160 (blister pack)

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