

NEW ZEALAND CONSUMER MEDICINE INFORMATION

RISPERIDONE TABLETS

Risperidone 0.5 mg, 1 mg, 2 mg, 3 mg, 4mg, 6 mg

What is in this leaflet

This leaflet answers some of the common questions about RISPERIDONE TABLETS.

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 using RISPERIDONE TABLETS, 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 are RISPERIDONE TABLETS used for

RISPERIDONE TABLETS belong to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

They are 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.
- treatment of acute mania associated with bipolar 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 TABLETS help 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. If you want more information, ask your doctor. It is only available with a doctor's prescription.

RISPERIDONE TABLETS are not addictive.

Before you use RISPERIDONE TABLETS

When you must not use it

Do not use RISPERIDONE TABLETS if:

- 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 use it

RISPERIDONE TABLETS should be used with caution in some patients.

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

- heart problems, particularly 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 or heart failure
- 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
- diabetes – unusual thirst, tiredness, blurred vision, upset stomach or need to urinate are common signs of high blood sugars
- epilepsy, seizures or fits
- continuous and/or painful erections (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 have been seen in patients taking RISPERIDONE TABLETS. Blood clots in the lungs can be fatal.

- low white blood cell count

As dangerously low numbers of certain types of white blood cells needed to fight infection in your blood has been seen very rarely with patients taking RISPERIDONE TABLETS, your doctor may check your white blood cell counts. Tell your doctor if you know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).

- Planned eye surgery

During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.

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 RISPERIDONE TABLETS temporarily prior to your eye surgery.

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

RISPERIDONE TABLETS may make you sweat less, causing your body to overheat.

- take any medicines for any other condition

Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will advise you whether or not you should take RISPERIDONE TABLETS.

Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, or difficulty in feeding may occur in newborns, if a mother uses the medicine in the last trimester of her pregnancy.

Tell your doctor if you are breast-feeding or intend to breast-feed.

Risperidone is excreted in breast milk. It is recommended that you do not breast-feed while taking the medicine.

Taking other medicines

RISPERIDONE TABLETS can increase the effect of other medicines which slow your reactions.

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

Ask your doctor or pharmacist before taking any other medicines. RISPERIDONE TABLETS can increase the effects of medicines which slow your reactions. These include herbal treatments and those bought in a pharmacy or supermarket.

Some medicines may interfere with RISPERIDONE TABLETS and affect how it works. Tell your doctor if you are taking:

- diuretics like furosemide, a drug used to treat high blood pressure, or to treat 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 furosemide is also taken with RISPERIDONE TABLETS.
- alcohol and medicines that reduce the ability to react (e.g. sleeping tablets, “tranquillisers”, strong pain-killers, certain antihistamines and certain antidepressants).
- medications that may change the electrical activity of the heart, such as but not restricted to: medicines for malaria, heart rhythm disorders, allergies, other antipsychotics, antidepressants, water tablets or other medicines affecting body salts (sodium, potassium, magnesium).
- medicines to treat Parkinson's disease (dopamine agonists, e.g. levodopa) may counteract RISPERIDONE TABLETS
- medicines to treat epilepsy
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).
- medicines for your heart or blood pressure, as taking these medicines together with RISPERIDONE TABLETS may cause the blood pressure to drop too low.

Some medicines, when taken together with RISPERIDONE TABLETS, may increase or decrease the level of risperidone in your blood. Therefore, tell your doctor if you start and/or stop taking any of the below medicines, since your doctor may need to change the dose.

Medicines that may increase the level of risperidone in your blood include:

- medicines to treat depression and various anxiety disorders, such as fluoxetine and paroxetine;
- medicines used to treat fungal infections such as itraconazole and ketoconazole;

- certain medicines used in the treatment of HIV/AIDS, such as ritonavir;
- verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm;
- sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.

Medicines that may reduce the level of RISPERIDONE TABLETS in your blood include:

- carbamazepine, a medicine mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face);
- rifampicin, a medicine for treating some infections.

How to use RISPERIDONE TABLETS

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 TABLETS 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 TABLETS 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 twice a day 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 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 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 drug called a mood stabiliser as well as RISPERIDONE TABLETS.

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 Disruptive Behaviour Disorders in Adults and Children

For people who weigh 50 kg or more, the usual starting dose is 0.5 mg 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 many RISPERIDONE TABLETS you need.

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 many RISPERIDONE TABLETS you need.

When to take it

RISPERIDONE TABLETS 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 TABLETS either with or between meals.

How to take it

Swallow RISPERIDONE TABLETS with water or other liquid.

Do not halve the tablets.

It is very important that you take the correct amount of RISPERIDONE 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 long to take it

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

RISPERIDONE TABLETS help control your condition but does not cure it. Therefore, you must take RISPERIDONE TABLETS every day.

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

If you forget to take RISPERIDONE TABLETS

- 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 one you missed.
- If you forget to take RISPERIDONE TABLETS 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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too many RISPERIDONE TABLETS. Do this even if there are no signs of discomfort or poisoning.

You can contact the Poisons Information Centre by dialling:

- New Zealand: 0800 POISON or 0800 764 766.

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

You should do this even if there are no signs of discomfort of poisoning.

While you are using RISPERIDONE TABLETS

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 TABLETS can cause weight gain. Your doctor may monitor your body weight or recommend strategies to assist with weight management.

You should make sure you are not pregnant.

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

than six months while taking RISPERIDONE TABLETS.

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 are symptoms of a condition called tardive dyskinesia, which may develop in people taking antipsychotic medicines, including RISPERIDONE TABLETS. This condition is more likely to occur during long term treatment with RISPERIDONE TABLETS, especially in older 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 are treating you that you are taking RISPERIDONE TABLETS.

Try to drink plenty of water, especially if you are elderly and taking furosemide (a diuretic). This will help decrease your risk of certain side effects.

Things you must not do

Do not drink alcohol.

RISPERIDONE TABLETS can increase the effects of alcohol.

Things to be careful of

Be careful driving or operating machinery until you know how RISPERIDONE TABLETS affect you.

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

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 TABLETS

You may need medical treatment if you get some of the side effects.

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.

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:

- 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, e.g. in the neck, back, ear, hands, or feet
- falling
- headache
- trembling, muscle weakness, unsteadiness on your feet, lack of coordination or slow, shuffling walk (symptoms of Parkinsonism)

behavioural changes such as:

- irritability or agitation
- unusual anxiety or nervousness

muscle, joint, nerve or movement changes such as:

- shaking or trembling
- fatigue or weakness
- muscle stiffness
- muscles aches or pains
- uncontrolled muscle spasms, twitching, jerking or writhing movements
- joint swelling or pain
- walking abnormally or with difficulty
- restlessness in the legs or difficulty sitting still
- abnormal posture, such as rigid body movements and persistent abnormal positions of the body

other changes such as:

- cold or “flu-like” symptoms e.g. 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)
- fever, chills, shortness of breath, cough, phlegm and occasionally blood (signs of pneumonia)
- nosebleeds
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (signs of decreased red blood cells)
- discharge with itching of the eyes and crusty eyelids
- unexplained weight gain
- unexplained increased or decreased in appetite
- indigestion, abdominal discomfort or pain, diarrhoea or constipation
- nausea or vomiting
- dry mouth or excessive thirst
- drooling
- difficulty swallowing
- acne
- dry skin
- dandruff
- rash, red skin or itchy skin
- skin infection
- thickening of the skin resulting in warts, corns, calluses
- swelling of any part of your body, e.g. hands, ankles or feet
- frequent daytime urination in children
- some loss of bladder control, bedwetting
- inability to or feeling burning pain when passing urine
- sexual function disturbances – problems with ejaculation
- unusual secretion of breast milk
- breast abnormalities - breast discomfort or swelling or unusual secretion of breast

milk

- dizziness on standing up, especially when getting from a sitting or lying down position
- missed or irregular menstrual periods
- involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk
- pneumonia, infection
- blurry vision, eye rolling, involuntary movement of the eyes
- sexual dysfunction, priapism (prolonged erection)
- vertigo
- hardening of the skin
- an increase of CPK (creatin 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 TABLETS 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:

Hypersensitivity reactions

- 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

Heart or blood pressure problems such as:

- 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

Tardive dyskinesia (uncontrollable twitching or jerking movements of the tongue, face, mouth, jaw, arms and legs)

- 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 may be serious side effects of RISPERIDONE TABLETS. You may need urgent medical attention.

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

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

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 using RISPERIDONE TABLETS

Storage

Keep RISPERIDONE TABLETS 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 TABLETS 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 TABLETS if the appearance of the tablets has changed.

Disposal

If your doctor tells you to stop taking RISPERIDONE TABLETS 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 TABLETS

You can identify RISPERIDONE TABLETS by their colour and shape. This is important because there are 6 types of RISPERIDONE TABLETS, each containing a different amount of risperidone:

- 0.5 mg are brick red coloured, round, biconvex, film coated tablets plain on both sides
- 1 mg are white to off-white, capsule shaped, biconvex, film coated tablets plain on both sides
- 2 mg are light orange coloured, capsule shaped, biconvex, film coated tablet with a break line on one side and plain on the other side
- 3 mg are light yellow coloured, capsule shaped, biconvex, film-coated tablet plain on both sides
- 4 mg are green coloured, capsule shaped, biconvex, film coated tablets plain on both sides
- 6 mg are yellow coloured, biconvex, film coated tablets, plain on both sides

All strengths come in boxes of 60 tablets, except 0.5 mg tablets which are also available in blister packs of 20 tablets.

Ingredients

RISPERIDONE TABLETS contain the active ingredient risperidone.

RISPERIDONE TABLETS also contain the following inactive ingredients:

- Lactose
- Maize starch
- Microcrystalline cellulose
- Sodium lauryl sulphate
- Colloidal silicon dioxide
- Purified talc
- Magnesium stearate
- Hypromellose
- Propylene Glycol

RISPERIDONE TABLETS may also contain titanium dioxide, ferric oxide, sunset yellow (E110), quinolone yellow (E104) and indigo carmine (E132) as colouring agents.

Sponsor Details

RISPERIDONE TABLETS is supplied in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

Date of Preparation

This leaflet was prepared on 29 July 2025