

OZIDAL

Risperidone Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Ozidal (risperidone) tablets.

It does not contain all of 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 it is expected to have for you.

If you have any concerns about using Ozidal, ask your doctor or pharmacist. Your doctor and pharmacist have more information.

Keep this leaflet with your Ozidal tablets. You may need to read it again.

What Ozidal is used for

Ozidal is used to treat symptoms of schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action.

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

Ozidal 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.

Ozidalis 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.

Ozidal 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.

Ozidal can also be used to treat behavioural symptoms of autism in children and adolescents.

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

Ozidal 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.

Ozidal is not addictive.

Before you take Ozidal

When you must not use it

Do not use Ozidal:

- 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 you are intolerant to lactose. This medicine contains small quantities of the inactive ingredient lactose. In case your doctor has told you that you have intolerance to some sugars, you must not take these tablets and should talk to your doctor. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption (which might cause pain in the abdomen, cramps, diarrhoea and gas after taking food) should not take these tablets.
- 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.
- After the expiry date printed on the pack. If you take it after the expiry date has passed, it may not work as well or may cause harm.
- 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)
- restlessness or difficulty sitting still (akathisia)

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

Avoid alcoholic beverages until you have discussed their use with your doctor. **Ozidal** can increase the effect of alcohol. You should not drink alcohol while taking Ozidal.

Taking other medicines

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

Some medicines may affect the way other medicines work.

In particular tell your doctor if you are taking:

- sleeping tablets, tranquillisers, pain-killers, antihistamines
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face), as it may decrease the level of risperidone in your blood
- medicines to treat Parkinson's disease or 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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking **Ozidal**.

In studies in elderly patients with dementia where risperidone was compared with a dummy pill, the death rate was 3.1% with the dummy pill and slightly higher at 4% with risperidone. 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).

Elderly People

Elderly people should take less **Ozidal** than is prescribed for other adults (see "How to take it").

Before you start to use it

Tell your doctor if you have allergies to

- any other medicines
- any other substance such as foods, preservatives or dyes

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

Your doctor will advise you whether or not you should take Ozidal. Agitation, muscle stiffness, unusual muscle slackness, shaking, drowsiness, breathing disorder and difficulty in feeding, all of which are reversible, may occur in newborns, if a mother used risperidone in the last trimester of her pregnancy.

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

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

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

- Heart or blood vessel diseases, including low blood pressure. Low blood pressure can result from using risperidone together with medicines to treat high blood pressure. So, if you need to use both risperidone and medications to reduce blood pressure, consult your doctor. Risperidone 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.
- dehydration
- kidney or liver problems
- Parkinson's disease
- dementia or Lewy body dementia
- epilepsy
- low potassium levels (hypokalaemia)
- breast cancer
- disease of the pituitary gland
- diabetes
- disease of the blood vessels of the brain including stroke

Using Ozidal

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 much to take

Take only when prescribed by your doctor.

Ozidal 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 **Ozidal**, 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 **Ozidal** 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 milligrams 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 milligrams twice a day.

Ozidal 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 2 mg 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 2 mg and 6 mg a day. Your doctor may decide you should take another drug called a mood stabiliser as well as **Ozidal**.

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 most suitable dose 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 **Ozidal** you need.

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

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

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

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

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

When and how to take it

Ozidal tablets should be swallowed with water or other liquid.

You may take **Ozidal** either with or between meals.

How long to take it

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

Do not let yourself run out of medicine over the weekend or on holidays.

If you forget to take it

If you forget to take **Ozidal**, 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 **Ozidal** 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 the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Ozidal. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Please keep these phone numbers handy.

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 Ozidal

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.

Contact your doctor if you develop restlessness and an overwhelming urge to move, pace, swing the legs while seated, rock from foot to foot or both, as these could be associated with akathisia.

Visit your doctor regularly for check ups.

If you suffer from sugar diabetes your doctor may monitor your blood sugar levels regularly to check for worsening of glucose control.

Pre-menopausal women should tell their doctor if they do not have a period for more than six months while taking Ozidal.

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

Try to eat a moderate diet. **Ozidal** can cause weight gain.

Things you must not do

- Do not take **Ozidal** 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 lower the dosage without checking with your doctor.
- Do not drink alcohol. **Ozidal** can increase the effects of alcohol.

Things to be careful of

- Ask your doctor before taking any other medicines. **Ozidal** 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 **Ozidal** affects you. **Ozidal** may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to **Ozidal** 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 **Ozidal**.

Side Effects

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

Ozidal helps most people but it may have some unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, but most of the time they are not. Risperidone 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.

Below is a list of possible side effects you could get while taking **Ozidal**:

- 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, slow heart rate, heart beat irregularities

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

The following may occur less often:

- drowsiness, tiredness, difficult 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 **Ozidal** 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 **Ozidal** 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. Low blood sugar also has been reported.

IMPORTANT: If you experience high fever, stiff muscles, fast breathing, abnormal sweating or decreased 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.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

Ozidal is not addictive.

After using it

Storage

Keep **Ozidal 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 your tablets in the pack until it is time to take them.

If you take your tablets out of the pack they will not keep as well.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Do not use **Ozidal 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 **Ozidal** if the appearance of the tablets has changed.

Disposal

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

Product Description

What it looks like

- **Ozidal** 0.5 mg tablets are brown-coloured, film-coated, oval-shaped tablets with a scoreline on both sides and 'RSN' and '0.5' debossed on either side of the scoreline on one side, available in packs of 60 tablets.
- **Ozidal** 1 mg tablets are white, film-coated, capsule-shaped tablets with a scoreline on both sides and 'RSN' and '1' debossed on either side of the scoreline on one side, available in packs of 60 tablets.
- **Ozidal** 2 mg tablets are peach-coloured, film-coated, capsule-shaped tablets with a scoreline on both sides and 'RSN' and '2' debossed on either side of the scoreline on one side, available in pack of 60 tablets.
- **Ozidal** 3 mg tablets are yellow-coloured, film-coated, capsule-shaped tablets with a scoreline on both sides and 'RSN' and '3' debossed on either side of the scoreline on one side, available in pack of 60 tablets.

- **Ozidal** 4 mg tablets are green-coloured, film-coated, capsule-shaped tablets with a scoreline on both sides and 'RSN' and '4' debossed on either side of the scoreline on one side, available in pack of 60 tablets.

Ingredients

Active ingredient

- **Ozidal** 0.5 mg tablets - 0.5 mg of risperidone
- **Ozidal** 1 mg tablets - 1 mg of risperidone
- **Ozidal** 2 mg tablets - 2 mg of risperidone
- **Ozidal** 3 mg tablets - 3 mg of risperidone
- **Ozidal** 4 mg tablets - 4 mg of risperidone

Inactive ingredients

Lactose monohydrate, pregelatinised starch, microcrystalline cellulose, sodium lauryl sulphate, colloidal anhydrous silica and magnesium stearate. In addition the 0.5 mg tablet contains Opadry II 31G 56729 brown, 1 mg tablet contains Opadry 20H 58983 white, the 2 mg tablet contains Opadry II 31G 53291 orange, the 3 mg tablet contains Opadry II 31G 52408 yellow and the 4 mg tablet contains Opadry II 31G 51195 green.

Australian Registration Numbers

- **Ozidal** 0.5 mg tablets - AUST R 148964
- **Ozidal** 1 mg tablets - AUST R 148967
- **Ozidal** 2 mg tablets - AUST R 148968
- **Ozidal** 3 mg tablets - AUST R 148969
- **Ozidal** 4 mg tablets - AUST R 148970

Sponsor

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