

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using OZIDAL?

OZIDAL contains the active ingredient Risperidone. OZIDAL belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

For more information, see Section [1. Why am I using OZIDAL?](#) in the full CMI.

2. What should I know before I use OZIDAL?

Do not use if you have ever had an allergic reaction to Risperidone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use OZIDAL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OZIDAL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use OZIDAL?

Your doctor will decide the dose suitable for you. Swallow OZIDAL tablets with water or other liquid. Continue taking the tablets as long as your doctor tells you.

More instructions can be found in Section [4. How do I use OZIDAL?](#) in the full CMI.

5. What should I know while using OZIDAL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using OZIDAL. • Tell your doctor if you are pregnant or planning to become pregnant. • Ask your doctor or pharmacist before taking any other medicines. • Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water. • If you are pre-menopausal, tell your doctor if you do not have a period for more than six months while using this medicine, even if you are not pregnant
Things you should not do	• Do not stop taking your medicine, or change the dosage, without first checking with your doctor • Do not give this medicine to anyone else, even if they have same condition as you. • Do not use OZIDAL tablets beyond the expiry date even if it has been stored properly. • Do not use OZIDAL if the appearance of the tablets has changed.
Driving or using machines	• Avoid driving or operating machinery until you are sure OZIDAL does not affect your alertness.
Drinking alcohol	• Do not drink alcohol. OZIDAL can increase the effects of alcohol
Looking after your medicine	• Keep this medicine where children cannot reach it. • Keep your medicine in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using OZIDAL?](#) in the full CMI.

6. Are there any side effects?

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

For more information on common side effects, and other serious side effects, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI

OZIDAL

Active ingredient(s): *Risperidone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OZIDAL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OZIDAL.**

Where to find information in this leaflet:

- [1. Why am I using OZIDAL?](#)
- [2. What should I know before I use OZIDAL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use OZIDAL?](#)
- [5. What should I know while using OZIDAL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using OZIDAL?

OZIDAL contains the active ingredient Risperidone. It belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

OZIDAL 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. This condition is characterized 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 behaviors
- treatment of behavioral 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 behaviors such as aggression, impulsiveness and self-injury in children (over 5 years old), adolescents and adults who are intellectually disabled,
- treatment of behavioral symptoms of autism in children and adolescent.

OZIDAL helps 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. It is only available with a doctor's prescription.

If you want more information, ask your doctor.

OZIDAL is not addictive.

2. What should I know before I use OZIDAL?

Warnings

Do not use OZIDAL:

- if you are allergic to Risperidone, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
Signs of allergy include skin rash, itching, shortness of breath, and/or swollen face.
- 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.

Check with your doctor if you:

- have or have ever had any medical conditions, especially the following:
 - 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.
 - unusual excessive sweating or diarrhea, 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 OZIDAL.
 - sugar diabetes.
 - 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.
 - 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 can occur with OZIDAL. Blood clots in the lungs can result in death.
- 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 OZIDAL.
- have any eye surgery planned. 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 your OZIDAL temporarily prior to your eye surgery.
- you will be in a hot environment or do a lot of vigorous exercise. OZIDAL may make you sweat less, causing your body to overheat.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will advise you whether you should take OZIDAL.

Newborn babies of mother taking OZIDAL in their last trimester may be at risk of having difficulty feeding or breathing, shaking, muscle stiffness and/or weakness, sleepiness or agitation.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

As OZIDAL is excreted in breast milk, it is recommended that you do not breast-feed while taking the medicine.

3. What if I am taking other medicines?

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

In particular, tell your doctor if you are taking:

- sleeping tablets, tranquillizers, strong pain-killers, certain allergy medicines called antihistamines, certain antidepressants and alcohol.

- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).
- medicines used to treat bacterial infections such as rifampicin.
- medicines to treat fungal infections such as itraconazole and ketoconazole.
- medicines to treat HIV/AIDS, such as ritonavir and tipranavir.
- other medicines to treat mental illness or psychotic conditions
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder, such as fluoxetine, paroxetine, sertraline and fluvoxamine
- medicines for your heart or blood pressure
- verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- furosemide, a medicine used to treat high blood pressure and fluid build-up.
There is an increased risk of side effects or death in older people if furosemide is also taken with OZIDAL.
- medicines to treat epilepsy
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face)
- medicines to treat Parkinson's disease or a tremor.

Some medicines may interfere with OZIDAL and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OZIDAL.

4. How do I use OZIDAL?

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.

For Schizophrenia and Related Psychoses

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.

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 Elderly Patients with Schizophrenia or Related Psychoses

For older patients a starting dose of 0.5 mg twice a day in the morning and in the evening is used. 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 (or 0.5 mL of solution) 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 acute mania

The recommended starting dose is 2mg once a day. This may be gradually increased by your doctor to suit your needs.

Your doctor may decide you should take another medicine 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.

For Disruptive Behaviour Disorders in Adults and Children

For people who weigh 50 kg or more, the usual starting dose is 0.5 mg (or 0.5 mL of solution) 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 much OZIDAL you need.

OZIDAL cannot be recommended for use in children with disruptive behavior disorders under 5 years at the present time as there is little experience with the product in this group.

For Behavioral Disorders Associated with Autism in Children and Adolescents

For people weighing less than 20kg the usual starting dose is 0.25mg. This may be gradually increased by your doctor to suit your needs.

For people weighing 20kg or more the usual starting dose is 0.5mg. This may be gradually increased by your doctor to suit your needs.

Your doctor will advise you on how much OZIDAL you need.

When to take

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). You may take OZIDAL either with or between meals.

How to take it

Swallow OZIDAL tablets with water or other liquid.

How long to take it

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

OZIDAL helps control your condition but does not cure it. Therefore, you must take OZIDAL every day.

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

If you forget to use OZIDAL

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.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you forget to take OZIDAL 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.

If you use too much OZIDAL

If you think that you have used too much OZIDAL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

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

5. What should I know while using OZIDAL?

Things you should 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.
- Remind any doctor, dentist or pharmacist you visit that you are taking OZIDAL.

- Tell your doctor if you are pregnant or planning to become pregnant.
- If you are pre-menopausal, tell your doctor if you do not have a period for more than six months while using OZIDAL, even if you are not pregnant.
- 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 may be symptoms of a condition called Tardive Dyskinesia, which can develop in people taking antipsychotic medicines, including OZIDAL. This condition is more likely to occur during longer term treatment and in older women. In very rare cases, these symptoms may be permanent. However, if detected early, these symptoms are usually reversible.
- Ask your doctor or pharmacist 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, including herbal treatments and medicines that can be bought in a pharmacy or supermarket.
- Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water.
- 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.

Things you should not do

- Do not stop taking your medicine, or change the dosage, without first checking with your doctor.
- Do not drink alcohol. OZIDAL can increase the effects of alcohol.
- Avoid excessive eating. There is a possibility of weight gain when taking OZIDAL. Your doctor may monitor your body weight or recommend strategies to assist with weight management.
- Do not use OZIDAL tablets beyond the expiry date even if it has been stored properly.
- Do not use OZIDAL if the appearance of the tablets has changed.

Driving or using machines

Avoid driving or operating machinery until you are sure OZIDAL does not affect your alertness.

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

Drinking alcohol

Do not drink alcohol. Tell your doctor if you drink alcohol. OZIDAL can increase the effects of alcohol

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep OZIDAL tablets in a dry place where the temperature stays below 25°C. Protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• difficulty thinking, working or carrying out your usual daily activities because of: - headache - trembling, muscle weakness, unsteadiness on your feet, lack of coordination or slow, shuffling walk (symptoms of Parkinsonism). - 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 • muscle, joint, nerve or movement changes such as:	Speak to your doctor if you have any of these less serious side effects and they worry you.

- shaking or trembling - fatigue or weakness - muscle stiffness - restlessness in the legs or difficulty sitting still - 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. • behavioural changes such as: - irritability or agitation - unusual anxiety or nervousness • 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) - 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 the eyes and crusty eyelids - unexplained weight gain - unexplained increase or decrease in appetite - indigestion, stomach discomfort or pain, diarrhoea or constipation - nausea or vomiting - 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, e.g. hands, ankles or feet - inability to or feeling burning pain when passing urine - some loss of bladder control - bedwetting - frequent daytime urination in children - sexual function disturbances - problems with ejaculation		- breast abnormalities - breast discomfort or swelling or unusual secretion of breast milk - 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 - 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.					
Serious side effects							
<table><tr><th>Serious side effects</th><th>What to do</th></tr><tr><td> • Signs of heart or blood pressure problems including: - 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 - evere muscle stiffness or fits • Involuntary movements of the tongue, face, mouth, jaw, 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. </td><td> Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. </td></tr></table>		Serious side effects	What to do	• Signs of heart or blood pressure problems including: - 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 - evere muscle stiffness or fits • Involuntary movements of the tongue, face, mouth, jaw, 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.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.		
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If you have them, you may have had a serious allergic reaction to OZIDAL. • Sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What OZIDAL contains

Active ingredient (main ingredient)	risperidone
Other ingredients (inactive ingredients)	Lactose monohydrate Pregelatinised starch Microcrystalline cellulose Sodium lauryl sulphate Colloidal anhydrous silica Magnesium stearate Opadry II 31G 56729 brown (0.5 mg tablet) Opadry 20H 58983 white (1 mg tablet) Opadry II 31G 53291 orange (2 mg tablet) Opadry II 31G 52408 yellow (3 mg tablet)
Potential allergens	Sugar as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What OZIDAL 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. AUST R 148964

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. AUST R 148967

OZIDAL 2 mg tablets are peach-coloured, film-coated, capsule-shaped tablets with a scoreline on both sides and 'RSN' and '2' debossed oneither side of the scoreline on one side, available in pack of 60 tablets. AUST R 148968

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. AUST R 148969

Who distributes OZIDAL

Sun Pharma ANZ Pty Ltd

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Australia
customerservice.aus@sunpharma.com
Tel: 1800 726 229

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