

Consumer Medicine Information (CMI) summary

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

1. Why am I taking RIXADONE?

RIXADONE contains the active ingredient Risperidone. RIXADONE 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 taking RIXADONE?](#) in the full CMI.

2. What should I know before I take RIXADONE?

Do not take 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 take RIXADONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RIXADONE 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 take RIXADONE?

Swallow RIXADONE tablets with water or other liquid.

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

5. What should I know while taking RIXADONE?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are taking RIXADONE. - 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. - Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water.
Things you should not do	Do not take RIXADONE if the appearance of the tablet has changed.
Driving or using machines	Avoid driving or operating machinery until you are sure RIXADONE does not affect your alertness.
Drinking alcohol	Do not drink alcohol. RIXADONE can increase the effects of alcohol.
Looking after your medicine	Keep your tablets in a cool, dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Like all medicines, RIXADONE can cause side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention and some may require urgent care.

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

RIXADONE®

Active ingredient(s): *Risperidone*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking RIXADONE?

RIXADONE contains the active ingredient risperidone.

RIXADONE belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

RIXADONE is taken for the:

- **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 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 adolescents.**

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

RIXADONE has been approved for the uses mentioned above. However, your doctor may prescribe it for another use.

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

RIXADONE is not addictive.

2. What should I know before I take RIXADONE?

Warnings

Do not take RIXADONE if:

- you have an allergy to:
 - o any medicine containing risperidone
 - o any of the ingredients listed at the end of this leaflet
 - o any other similar medicinesSome of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin

Always check the ingredients to make sure you can take this medicine.

- the expiry date printed on the pack has passed or 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 RIXADONE, talk to your doctor.

Check with your doctor if you:

- **have or have had any other medical conditions, especially the following:**
 - o 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.
 - o unusual excessive sweating or diarrhoea, dehydration or problems with your body temperature regulation
 - o kidney or liver problems
 - o you are prone to dizziness when standing up from lying or sitting position
 - o Parkinson's disease (a progressive movement and thinking disorder that tends to affect older people)
 - o dementia or Lewy body dementia - older people suffering dementia may be at increased risk of stroke or death with RIXADONE
 - o sugar diabetes - unusual thirst, tiredness, blurred vision, upset stomach or need to urinate are common signs of high blood sugars
 - o epilepsy, seizures or fits
 - o continuous and/or painful erections (called 'priapism')

- o involuntary movements or unusual restlessness or difficulty sitting still
- o suicidal thoughts or past suicide attempts
- o low blood potassium levels (hypokalaemia)
- o breast cancer
- o cancer of the pituitary gland
- o Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the tongue, face, mouth, jaw, arms and legs)
- o 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).
- o 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 RIXADONE. Blood clots in the lungs can result in death.
- o 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 RIXADONE.

- **have any eye surgery planned.**

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 colored 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 your RIXADONE temporarily prior to your eye surgery.

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

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

- **take any medicines for any other condition.**

RIXADONE should be taken with caution in some patients.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking RIXADONE.

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 planning to become pregnant.

Your doctor will advise you whether you should take RIXADONE. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, or difficulty in

feeding may occur in newborns, if a mother has taken RIXADONE in the last trimester of her pregnancy.

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

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

Children and adolescents

RIXADONE 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.

RIXADONE 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.

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.

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.

Some medicines may interfere with RIXADONE and affect how it works. These include:

- RIXADONE can enhance the effects of alcohol and medicines that reduce the ability to react (e.g., sleeping tablets, "tranquillisers", strong painkillers, certain antihistamines, certain antidepressants). So don't drink alcohol and only take such medicines if your doctor prescribes them.
- Some medicines for treating Parkinson's disease or a tremor (dopamine agonists, e.g. levodopa) may counteract RIXADONE.
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).
- other medicines to treat mental illness or psychotic conditions
- if you are taking medicines for high blood pressure, consult your doctor, as taking these medicines together with RIXADONE may cause the blood pressure to drop too low.
- RIXADONE should be taken with caution when taking 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).
- Taking RIXADONE with furosemide (frusemide), a medicine taken to treat conditions such as heart failure, high blood pressure and fluid build-up. There is an increased risk of side effects or death in older

people if furosemide (frusemide) is also taken with RIXADONE.

- medicines to treat epilepsy.

Some medicines, when they are taken together with RIXADONE, may increase or decrease the level of RIXADONE 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 effect of RIXADONE include:

- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder, such as fluoxetine and paroxetine, sertraline and fluvoxamine;
- medicines to treat fungal infections such as itraconazole and ketoconazole;
- certain medicines taken in the treatment of HIV/AIDS, such as ritonavir and tipranavir;
- verapamil, a medicine taken to treat high blood pressure and/or abnormal heart rhythm;

Medicines that may reduce the effect of RIXADONE include:

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

These medicines may be affected by RIXADONE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How do I take RIXADONE?

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.

- **For Schizophrenia and Related Psychoses**

The usual starting dose of RIXADONE 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 (in the morning and in the evening 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 (or 0.5 mL of solution) twice a day is usual. This may be gradually increased by your doctor to suit your needs.

- **For acute 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 medicine called a mood stabiliser as well as RIXADONE.

- **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**

- o 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.
- o 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.
- o Your doctor will advise you on how much RIXADONE you need.

- **For Behavioural Disorders Associated with Autism in Children and Adolescents**

- o For people weighing less than 20 kg the usual starting dose is 0.25mg. This may be gradually increased by your doctor to suit your needs.
- o For people weighing 20 kg or more the usual starting dose is 0.5mg. This may be gradually increased by your doctor to suit your needs.
- o Your doctor will advise you on how much RIXADONE you need.

- **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.

When to take RIXADONE

- RIXADONE 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 RIXADONE either with or between meals.

How to take it

- Swallow RIXADONE tablets with water or other liquid.
- Take your medicine at about the same time each day.

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

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

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

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

If you forget to take RIXADONE

If you forget to take RIXADONE, 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.

If you forget to take RIXADONE 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 take too much RIXADONE

If you think that you have or anyone else has taken too much RIXADONE, urgent medical attention may be needed.

You should immediately:

phone the Poisons Information Centre (in Australia **telephone 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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 or poisoning.

5. What should I know while taking RIXADONE?

Things you should do

- **Follow your doctor's instructions carefully and seek your doctor's advice before changing or stopping treatment.**
- **Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water.**
- **Avoid excessive eating.** There is a possibility of weight gain when taking RIXADONE. Your doctor may monitor your body weight or recommend strategies to assist with weight management.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking RIXADONE.

- If you are pre-menopausal, tell your doctor if you do not have a period for more than six months while taking RIXADONE, even if you are not pregnant.

Call your doctor straight away 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 RIXADONE. 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.

Things you should not do

- Do not take RIXADONE if the appearance of the tablets has changed. Driving or using machines

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

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

Drinking alcohol

Do not drink alcohol.

RIXADONE can increase the effects of alcohol.

Looking after your medicine

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

If you take the tablets out of the pack, they may not keep well.

Keep your tablets where the temperature stays below 25°C.

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

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.

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 take RIXADONE 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 take RIXADONE if the appearance of the tablets has changed.

Getting rid of any unwanted medicine

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

Do not take 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.

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: • 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	Tell your doctor if you notice any of these less serious side effects and they worry you. These are mild side effects.

Less serious side effects	What to do
• 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) • 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 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 • dandruff • 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	

Less serious side effects	What to do
- 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 (creatine 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

Serious side effects	What to do
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 If you have them, you may have a serious allergic reaction to RIXADONE. 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:	Tell your doctor immediately, or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects. These are very serious side effects.

Serious side effects	What to do
- 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) Other - sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes).	

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 RIXADONE contains

Active ingredient (main ingredient)	risperidone (0.5 mg, 1 mg, 3 mg, 3 mg and 4mg) per tablet
Other ingredients (inactive ingredients)	- lactose monohydrate - microcrystalline cellulose - pregelatinised maize starch - sodium lauryl sulfate

	• colloidal anhydrous silica • magnesium stearate • purified talc • hypromellose • propylene glycol • titanium dioxide Additionally, the following tablet strengths also contain the following colouring agents: • RIXADONE 0.5 mg ◦ iron oxide black ◦ iron oxide red • RIXADONE 2 mg ◦ sunset yellow FCF aluminium lake • RIXADONE 3 mg ◦ quinoline yellow aluminium lake • RIXADONE 4 mg ◦ quinoline yellow aluminium lake ◦ indigo carmine aluminium lake
Potential allergens	• egg products • sugars as lactose

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Phone: 1800 274 276

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RIXADONE® is a Viatris company trade mark

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

What RIXADONE looks like

- **RIXADONE 0.5 mg:** Red-brown, round, biconvex, film coated tablet with break line on one side and debossed "0.5" on the other side (AUST R 199179).
- **RIXADONE 1 mg:** White, round, biconvex, film coated tablet with break line on one side and debossed "1" on the other side (AUST R 199178).
- **RIXADONE 2 mg:** Orange, round, biconvex, film coated tablet with break line on one side and debossed "2" on the other side (AUST R 199180).
- **RIXADONE 3 mg:** Yellow, round, biconvex, film coated tablet with break line on one side and debossed "3" on the other side (AUST R 199182).
- **RIXADONE 4 mg:** Green, round, biconvex, film coated tablet with break line on one side and debossed "4" on the other side (AUST R 199181).

RIXADONE 0.5 mg tablets are available in blister packs of 20 and 60 tablets.

RIXADONE 1 mg, 2 mg, 3 mg and 4 mg tablets are available in blister packs of 60 tablets.

Who distributes RIXADONE

Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond