

RIXADONE®

risperidone

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions about RIXADONE. 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 RIXADONE against the benefits they expect it will have for you.

If you have any concerns about using RIXADONE, 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 RIXADONE is used for

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

It is used for:

- treatment of sudden (acute) and long-term (chronic) schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action,
- short term treatment of acute mania associated with bipolar 1 disorder. 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.

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

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.

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

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

RIXADONE is not addictive.

It is only available with a doctor's prescription.

Before you take RIXADONE

When you must not take it

Do not use RIXADONE if you have an allergy to:

- any medicine containing risperidone
- any of the ingredients listed at the end of this leaflet
- any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

RIXADONE should be used with caution in some patients.

Tell 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 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 RIXADONE
- sugar diabetes
- unusual thirst, tiredness, blurred vision, upset stomach or need to urinate - common signs of high blood sugar
- 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 RIXADONE. 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 RIXADONE.

Tell your doctor if:

- **you 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

RIXADONE temporarily prior to

your eye surgery.

- **you are pregnant or planning to become pregnant.**

Your doctor will advise you whether you should take RIXADONE.

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

- **you are breast-feeding.**

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

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

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

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any 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
- Tranquillisers
- Strong pain-killers
- Certain allergy medicines called antihistamines
- 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 such as verapamil
- Furosemide (frusemide), 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 (frusemide) is also taken with RIXADONE.

- Medicines to treat epilepsy such as 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.

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Taking it for the first time

At the start of treatment, you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

How to take RIXADONE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will decide the dose suitable for you.

Do not change or stop the required dosage without consulting your doctor first.

Important note: never take more tablets than your doctor tells you to take.

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 (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.

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 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

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 RIXADONE you need.

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.

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 much RIXADONE you need.

When to take it

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 for

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 one 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

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 [Medicine name]. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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 RIXADONE

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.

Tell all doctors, dentists, and pharmacists who are treating you that you are taking RIXADONE.

Ask your doctor or pharmacist before taking any other medicines.

RIXADONE 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.

Tell your doctor if you are 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 taking RIXADONE, 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 are 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.

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

Do not drink alcohol

RIXADONE can increase the effects of alcohol.

Things to be careful of

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

RIXADONE may cause dizziness or 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.

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.

Side effects

All medicines can have some unwanted side effects. Sometimes they are serious, but most of the time they are not. 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 RIXADONE.

Tell your doctor if you notice any of the following and they worry you:

- **difficulty thinking or working 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
- 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 (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.

These are mild side effects of RIXADONE 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:

- **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
 - severe 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.**

If you have them, you may have had a serious allergic reaction to RIXADONE.

- **sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)**

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above 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.

After taking RIXADONE

Storage

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 in a cool, dry place where the temperature stays below 25°C.

Do not store RIXADONE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use 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 use RIXADONE if the appearance of the tablets has changed.

Disposal

If your doctor tells you to stop taking RIXADONE or if it has passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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.

RIXADONE 1 mg: White, round, biconvex, film coated tablet with break line on one side and debossed "1" on the other side.

RIXADONE 2 mg: Orange, round, biconvex, film coated tablet with break line on one side and debossed "2" on the other side.

RIXADONE 3 mg: Yellow, round, biconvex, film coated tablet with break line on one side and debossed "3" on the other side.

RIXADONE 4 mg: Green, round, biconvex, film coated tablet with break line on one side and debossed "4" on the other side.

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.

Ingredients

RIXADONE tablets contain either 0.5 mg, 1 mg, 2 mg, 3 mg or 4 mg (milligrams) of risperidone as the active ingredient.

The tablets also contain the following 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

RIXADONE contains egg products and sugars as lactose.

Sponsor

RIXADONE is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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RIXADONE 1 mg: AUST R 199178

RIXADONE 2 mg: AUST R 199180

RIXADONE 3 mg: AUST R 199182

RIXADONE 4 mg: AUST R 199181

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