

# Rixadone

contains the active ingredient risperidone

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some 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 taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Rixadone is used for

This medicine belongs to a group of medicines called antipsychotics. It is used to treat conditions which affect the way you think, feel and/or act. Rixadone may be taken for both sudden (acute) and long-lasting (chronic) disorders.

Rixadone is also used to treat behavioural problems in patients with dementia (decline in mental activity). These problems include:

- \* aggression
- \* morbid suspiciousness
- \* agitation
- \* wandering

This medicine can also be used to treat conduct and other disruptive behaviours such as aggression,

impulsiveness and self-injury in children over 5 years, adolescents and adults who are intellectually disabled.

Rixadone helps to correct chemical imbalances in the brain, which may cause these conditions.

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

Your doctor may have prescribed it for another reason.

Rixadone is not addictive.

### Before you take Rixadone

#### When you must not take it

**Do not take Rixadone if you are allergic to risperidone or any of the ingredients listed at the end of this leaflet.**

**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

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have ever had any of the following medical conditions:**

- \* heart or blood vessel problems
- \* stroke or transient ischaemic attack (temporary reduction in blood flow to the brain)
- \* hypertension
- \* dehydration
- \* kidney or liver problems
- \* Parkinson's disease
- \* dementia / dementia with Lewy Bodies
- \* epilepsy
- \* breast cancer or tumours in the pituitary gland
- \* disease of the blood vessels of the brain, including stroke
- \* Neuroleptic Malignant Syndrome (a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- \* Tardive dyskinesia (uncontrollable twitching or jerking movements of the arms and legs).

**Tell your doctor if you are pregnant or plan to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you are breast-feeding.**

The active ingredient in Rixadone passes into breast milk and there is a

possibility that your baby may be affected. It is recommended that you do not breast-feed while taking this medicine.

**Your doctor will advise you whether or not you should take Rixadone.**

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

**Some medicines and Rixadone may interfere with each other. These include:**

- \* medicines to treat heart problems or high blood pressure, such as beta-blockers or frusemide. Studies in elderly patients have shown that taking Rixadone with frusemide may be harmful. Your doctor will decide if you can take Rixadone and if the dose will need to be changed
- \* sleeping tablets or tranquillisers
- \* some strong pain killers
- \* antihistamines
- \* carbamazepine, a medicine used for epilepsy or trigeminal neuralgia (sudden, repeated attacks of facial pain)
- \* medicines to treat Parkinson's disease
- \* medicines to treat epilepsy
- \* medicines to treat depression, panic or anxiety disorders, obsessive-compulsive disorder
- \* medicines to treat pre-menstrual dysphoric disorder
- \* medicines to relieve nausea or vomiting
- \* other medicines to treat mental illnesses or psychotic conditions.

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.

---

## **How to take Rixadone**

---

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

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack, ask your doctor or pharmacist.**

### ***How much to take***

Your doctor will tell you how many Rixadone tablets to take and for how long you should continue to take them. This will vary from person to person and your doctor will adjust the number and strength of the tablets to suit you.

### **For Schizophrenia and Related Psychoses**

The usual starting dose is 1 mg twice a day. This dose will be increased gradually 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.

Your doctor will determine the most suitable dose for you for long-term treatment.

Rixadone is not recommended for use in children with schizophrenia under 15 years, as there is not enough experience with the product in this age group.

### **For Elderly Patients with Schizophrenia or Related Psychoses**

In elderly patients, the usual starting dose is 0.5 mg (half a 1 mg tablet) twice a day (in the morning and in the evening). This dose may be

gradually increased by your doctor to 1 to 2 mg twice a day.

### **Patients with impaired kidney and liver function**

The usual starting dose is 0.5 mg (half a 1 mg tablet) twice a day (in the morning and in the evening).

This dose may be gradually increased by your doctor to 1 to 2 mg twice a day.

### **For Behavioural Problems in People with Dementia**

The usual starting dose is 0.25 mg twice daily. This dose may be gradually increased by your doctor to 0.5 to 1 mg twice a day.

From then on the dose can be taken once a day or twice a day according to your doctor's instructions.

### **For Disruptive Behaviour Disorders in Adults and Children**

For people who weigh 50 kg or more, the usual starting dose is 0.5 mg (half a 1 mg tablet) once a day. This 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. This 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.

Rixadone cannot be recommended for use in children with disruptive behaviour disorders under 5 years, as there is not enough experience with the product in this age group.

### ***How to take it***

Rixadone can be taken as a single dose, once a day, or in divided doses twice a day (in the morning and in the evening).

**Swallow the tablets with a glass of water.**

### ***When to take it***

**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.

Rixadone tablets can be taken with or without food.

### ***How long to take it for***

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

### ***If you forget to take it***

If you miss a tablet, take your next tablet as usual and continue your course.

Do not take more than one dose at a time to make up for the dose you missed.

If you are not sure what to do or have any questions about this, ask your doctor or pharmacist.

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 you or anyone else may have taken too much Rixadone. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

---

## **While you are taking Rixadone**

---

### ***Things you must do***

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Rixadone.

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

Keep all of your doctor's appointments so that your progress can be checked.

Follow your doctor's instructions carefully, and always consult your doctor before changing or stopping treatment.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

### ***Things you must not do***

Do not take Rixadone 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.

You should not drink alcohol while taking Rixadone.

Rixadone can increase the effects of alcohol and you might feel drowsy and less alert.

### ***Things to be careful of***

Always ask your doctor before taking any other medicines.

Rixadone can increase the effects of medicines which slow your reactions. These include herbal medicines and those bought in a pharmacy or supermarket.

Be careful driving or operating machinery until you know how Rixadone affects you.

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.

Avoid excessive eating as there is a possibility of weight gain when taking Rixadone.

---

## **Side effects**

---

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

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- \* sleeplessness
- \* headache
- \* drowsiness, tiredness
- \* dizziness
- \* difficult in concentrating
- \* somnolence, usually mild and short lasting may occur in children more often than in adults
- \* excessive saliva
- \* indigestion, abdominal pain, feeling sick (nausea), constipation
- \* sexual function disturbances
- \* blocked nose
- \* weight gain
- \* 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.

- \* some women after taking Rixadone for a long time, may experience breast enlargement or get a discharge from the breasts. They may also experience irregular or heavy periods or absence of their periods.
- \* men may experience breast enlargement.

**Tell your doctor as soon as possible if you notice any of the following:**

- \* agitation, anxiety
- \* blurred vision
- \* fast heart beat
- \* trembling
- \* muscle stiffness
- \* restlessness in the legs
- \* loss of bladder control
- \* needing to pass urine more often or feeling more thirsty than usual. These may be signs of high blood sugar levels (hyperglycaemia).

The above list includes serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- \* symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- \* jerky movements and problems such as slowness, muscle stiffness, trembling and feeling restless. More saliva than normal, twitching or unusual movements of the tongue, face, mouth, jaw or throat, or rolling of the eyes.
- \* significant changes in your body temperature
- \* fits (convulsions)
- \* 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

- \* Neuroleptic Malignant Syndrome, a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure, muscular rigidity and severe convulsions.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people.

---

## 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 degrees 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.

### Disposal

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

---

## Product description

---

### What it looks like

Rixadone is available in 5 strengths:

- \* 0.5 mg red, round tablets marked "R" on one side and scored on the other.
- \* 1 mg white, oblong scored tablets marked "R" "1" on the scored side.
- \* 2 mg orange, oblong scored tablets marked "R" "2" on the scored side.
- \* 3 mg yellow, oblong scored tablets marked "R" "3" on the scored side.
- \* 4 mg green, oblong scored tablets marked "R" "4" on the scored side.

### Ingredients

The active ingredient in Rixadone is risperidone.

The tablets contain either 0.5, 1, 2, 3 or 4 mg of risperidone.

- \* The 0.5 mg tablets also contain lactose, cellulose-microcrystalline, starch-maize, silica- colloidal anhydrous, magnesium stearate, water-purified, hypromellose, titanium dioxide, Macrogol 400, and iron oxide red CI77491. Available in blister packs of 60 tablets.
- \* The 1 mg tablets also contain lactose, cellulose-microcrystalline, starch-maize, silica- colloidal anhydrous, magnesium stearate, water-purified, hypromellose, titanium dioxide, and Macrogol 400. Available in blister packs of 60 tablets.
- \* The 2 mg tablets also contain lactose, cellulose-microcrystalline, starch-maize, silica- colloidal anhydrous, magnesium stearate, water-purified, hypromellose, titanium dioxide, Macrogol 400, iron oxide red CI77491, and

quinoline yellow CI47005.  
Available in blister packs of 60 tablets.

\* The 3 mg tablets also contain lactose, cellulose-microcrystalline, starch-maize, silica- colloidal anhydrous, magnesium stearate, water-purified, hypromellose, titanium dioxide, Macrogol 400, and quinoline yellow CI47005. Available in blister packs of 60 tablets.

\* The 4 mg tablets also contain lactose, cellulose-microcrystalline, starch-maize, silica- colloidal anhydrous, magnesium stearate, water-purified, hypromellose, titanium dioxide, Macrogol 400, quinoline yellow CI47005 and indigotin CI73015. Available in blister packs of 60 tablets.

### **Supplier**

Rixadone is supplied in Australia by:

#### **Alphapharm Pty Limited**

Cnr. Wentworth Park Road & Bay Street

Glebe NSW 2037

Phone: (02) 9298 3999

ABN 93 002 359 739

[www.alphapharm.com.au](http://www.alphapharm.com.au)

#### Medical Information

Phone: 1800 028 365

Australian registration numbers:

0.5 mg Tablet: AUST R 127892

1 mg Tablet: AUST R 127894

2 mg Tablet: AUST R 127896

3 mg Tablet: AUST R 127906

4 mg Tablet: AUST R 127909

This leaflet was prepared on  
9 December 2008.