

RILUZOLE WINTHROP®

riluzole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Riluzole Winthrop.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits 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 this medicine.

You may need to read it again.

What Riluzole Winthrop is used for

The brand name of your medicine is Riluzole Winthrop. The active ingredient in the medicine is called riluzole.

Riluzole Winthrop is used to treat people with amyotrophic lateral sclerosis, which can cause muscle degeneration leading to muscle weakness. It is a form of Motor Neurone Disease.

Your doctor may have prescribed this medicine for another reason.

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

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

It is important to remember that you may not feel any different when you take Riluzole Winthrop. The benefits of using Riluzole Winthrop may not be noticeable to you. You should not stop taking Riluzole Winthrop without speaking to your doctor first.

Before you take it

When you must not take it

Do not take Riluzole Winthrop if you:

- have liver disease
- are pregnant or intend to become pregnant
- are breast feeding or intend to breastfeed

Do not if you are allergic to riluzole or any of the ingredients listed at the end of this leaflet.

Do not give this medicine to a child.

There is no experience with the use of this medicine in children.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any of the ingredients listed at the end of this leaflet.

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

This medicine is not recommended to be used during pregnancy.

Tell your doctor if you are breastfeeding or planning to breastfeed.

It is not known whether it passes into breast milk. Your doctor will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

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

- liver disease
- kidney disease
- lung disease

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you take this medicine.

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 store.

Some medicines and Riluzole Winthrop may interfere with each other. These include:

- theophylline - a medicine used to treat asthma.
- amitriptyline - a medicine used to treat depression
- tacrine - a medicine used in patients with Alzheimer's Disease
- some types of antibiotics eg. rifampicin and quinolones
- omeprazole - a medicine used to treat gastric ulcers

- some medicines used to treat depression eg. clomipramine and fluvoxamine
- diazepam - a medicine for sedation
- diclofenac - a medicine used to reduce pain and inflammation.

These medicines may be affected by Riluzole Winthrop, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will advise you.

Tell your doctor if you smoke and how much coffee you drink. Nicotine and caffeine may affect the amount of Riluzole Winthrop in your body.

How to take Riluzole Winthrop

How much to take

Your doctor or pharmacist will tell you how many Riluzole Winthrop tablets you should take, and when to take them.

The recommended dose is usually one tablet two times a day.

Do not take more than the dose your doctor has directed.

Talk to your doctor or pharmacist if you are unsure what dose to take.

You should not change the dosage without speaking to your doctor first.

How to take it

Swallow Riluzole Winthrop tablets with a full glass of water or other liquid.

Do not chew the tablets.

When to take it

Riluzole Winthrop should not be taken immediately before or after meals, especially meals which may contain food high in fat.

Riluzole Winthrop may not work as well if it is taken at the same time as your meals.

Take your prescribed dose at about the same time each day.

How long to take it

Do not stop taking Riluzole Winthrop unless your doctor tells you to, even if you feel better.

If you forget to take it

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 that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Riluzole Winthrop. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Riluzole Winthrop

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Riluzole Winthrop. If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Riluzole Winthrop.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

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

During your treatment with Riluzole Winthrop your doctor will do some

blood tests from time to time to check for any possible signs of liver damage.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking this medicine, or lower the dosage, without checking with your doctor.

Things to be careful of

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

This medicine may cause drowsiness or dizziness in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, 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 if you notice any of the following:

- stomach ache, nausea or vomiting
- headache
- joint stiffness
- skin problems eg. rash, flaking skin
- dizziness
- sleepiness

- weakness or loss of strength

These are the most common side effects of this medicine.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- irregular or fast heartbeat
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- swelling of the hands, feet or legs
- tingling sensations around the mouth
- shortness of breath or difficulty breathing

These may be serious side effects of Riluzole Winthrop. You may need urgent medical attention. Serious side effects are rare.

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

- Severe upper stomach pain, often with nausea and vomiting
- If your skin becomes itchy or yellow or if you start to bleed or bruise easily. You may be developing a liver problem.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

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

After taking Riluzole Winthrop

Storage

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

If you take the tablets out of the box or blister pack they may not keep well.

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

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

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 Riluzole Winthrop, or it has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Riluzole Winthrop tablets are white and capsule-shaped. Each tablet is engraved with the text RPR 202:

Each pack contains 56 tablets.

Ingredients

Each tablet contains 50 milligrams of riluzole.

The tablets also contain:

- anhydrous calcium hydrogen phosphate
- microcrystalline cellulose
- anhydrous colloidal silica
- magnesium stearate
- croscarmellose sodium
- hypromellose
- macrogol 6000
- titanium dioxide
- purified water

Manufacturer/Sponsor

Riluzole Winthrop is supplied in Australia by:

Sanofi-Aventis Australia Pty Ltd.12-24 Talavera RoadMacquarie Park NSW 2113

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