

Riluzole Sandoz®

riluzole film-coated tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Riluzole Sandoz.

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 the medicine.

You may need to read it again.

WHAT RILUZOLE SANDOZ IS USED FOR

This medicine 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.

It contains the active ingredient riluzole.

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.

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

BEFORE YOU TAKE RILUZOLE SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- riluzole, the active ingredient, or to any of the other ingredient(s) listed at the end of this leaflet under Product Description

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 if you have liver disease.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Riluzole Sandoz may pass into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child.

Safety and effectiveness in children have not been established.

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 had any of the following medical conditions:

- liver disease
- kidney disease
- lung disease.

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

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

If you have not told your doctor about any of the above, tell him/her before you start taking Riluzole Sandoz.

Taking other medicines

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

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

- theophylline used to treat asthma
- amitriptyline used to treat depression
- tacrine used in patients with Alzheimer's Disease
- omeprazole used to treat gastric ulcers
- diazepam used to treat sedation
- diclofenac used to reduce pain and inflammation
- some types of antibiotics e.g. rifampicin and quinolones

- some medicines used to treat depression e.g. clomipramine and fluvoxamine.

These medicines may be affected by Riluzole Sandoz 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.

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

HOW TO TAKE RILUZOLE SANDOZ

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, ask your doctor or pharmacist for help.

How much to take

The standard dose for this medicine is one tablet two times a day.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Riluzole Sandoz may not work as well and your problem may not improve.

How to take it

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

Do not chew them.

These tablets/capsules have a special coating to stop them dissolving until they have gone

through the stomach and into the intestines, where they can start to work. If you chew them, the coating is destroyed.

When to take it

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

Riluzole Sandoz 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.

How long to take it

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Take your dose as soon as you remember, and continue to take 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 that you missed.

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering 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 that you or anyone else may have taken too much Riluzole Sandoz. Do this

even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING RILUZOLE SANDOZ

Things you must do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

During your treatment with Rilutek 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 take Riluzole Sandoz 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.

Do not stop taking your 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 Riluzole Sandoz affects you.

This medicine may cause dizziness, and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do

anything else that could be dangerous.

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, 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:

- stomach ache, nausea or vomiting
- headache
- joint stiffness
- skin problems e.g. rash, flaking skin
- dizziness
- sleepiness
- weakness or loss of strength.

These are common side effects of the medicine.

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

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

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

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

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

AFTER TAKING RILUZOLE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Riluzole Sandoz 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

Riluzole Sandoz 50mg - white, capsule shaped, debossed with the text 'RLZ' on one side.

Available in blisters of 56 filmcoated tablets.

Ingredients

Active ingredients:

- Riluzole Sandoz 50 mg - 50 mg riluzole.

Inactive ingredients:

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

This medicine does not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
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Australia
Tel: 1800 634 500

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Australian Register Number(s)

50mg film-coated tablets: AUST R 167717 (blisters)