

Package leaflet: Information for the patient

Riluzole 50 mg Film-coated Tablets riluzole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Riluzole is and what it is used for
2. What you need to know before you take Riluzole
3. How to take Riluzole
4. Possible side effects
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1. What Riluzole is and what it is used for

What Riluzole is

The active substance in Riluzole is riluzole which acts on the nervous system.

What Riluzole is used for

Riluzole is used in patients with amyotrophic lateral sclerosis (ALS).

ALS is a form of motor neurone disease where attacks of the nerve cells responsible for sending instructions to the muscles lead to weakness, muscle waste and paralysis.

The destruction of nerve cells in motor neurone disease may be caused by too much glutamate (a chemical messenger) in the brain and spinal cord. Riluzole stops the release of glutamate and this may help in preventing the nerve cells being damaged.

Please consult your doctor for more information about ALS and the reason why this medicine has been prescribed for you.

2. What you need to know before you take Riluzole

Do not take Riluzole

- if you are **allergic** to riluzole or any of the other ingredients of this medicine (listed in section 6)
- if you have any **liver disease** or increased blood levels of some enzymes of the liver (transaminases)
- if you are **pregnant or breast-feeding**.

Warnings and precautions

Talk to your doctor or pharmacist before using Riluzole

- if you have any **liver problems**: yellowing of your skin or the white of your eyes (jaundice), itching all over, feeling sick, being sick
- if your **kidneys** are not working very well
- if you have any **fever**: it may be due to a low number of white blood cells which can cause an increased risk of infection

If any of the above applies to you, or if you are not sure, tell your doctor who will decide what to do.

Children and adolescents

If you are less than 18 years of age. The use of Riluzole is **not** recommended in children because there is no information available in this population.

Other medicines and Riluzole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

You must **not** take Riluzole if you are pregnant or think you may be pregnant, or if you are breast-feeding.

If you think you may be pregnant or are planning to breast-feed, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You can drive or use any tools or machines, unless you feel dizzy or light headed after taking this medicine.

3. How to take Riluzole

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet, twice a day.

The tablets should be taken by mouth, every 12 hours, at the same time of the day each day (e.g. in the morning and evening).

If you take more Riluzole than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department **immediately**. Signs of an overdose can include feeling dizzy or drowsy, or reduced consciousness including coma.

If you forget to take Riluzole

If you forget to take your tablet, leave out that dose completely and take the next tablet at the usual time.

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

IMPORTANT

Tell your doctor immediately

- if you experience an allergic reaction. Such reactions may appear in the form of anaphylaxis (a severe form of allergic reaction) with symptoms such as:
 - rash
 - swelling of the face, lips, mouth, tongue or throat (angioedema)
 - sudden wheezing, fainting or difficulty swallowing
- if you experience any **fever** (increase in temperature) because Riluzole may cause a decrease in the number of white blood cells. Your doctor may want to take a blood sample to check the number of white blood cells, which are important in fighting infections.
- if you experience any of the following symptoms: yellowing of your skin or the white of your eyes (jaundice), itching all over, feeling sick, being sick, as this may be signs of **liver disease** (hepatitis). Your doctor may do regular blood tests while you are taking Riluzole to make sure that this does not occur.
- if you experience cough or difficulties in breathing, as this may be a sign of lung disease (called interstitial lung disease).
- if you experience severe pain spreading from the abdomen to the back, as this may be signs of an inflamed pancreas (pancreatitis).

Other possible side effects

Very common side effects (may affect more than 1 in 10 people):

- feeling tired or weak
- feeling sick
- increased blood levels of some enzymes of the liver (transaminases).

Common side effects (may affect up to 1 in 10 people):

- headache
- dizziness
- numbness or tingling of the mouth
- sleepiness
- increase in heart beat
- vomiting
- diarrhoea
- abdominal pain
- pain

Uncommon side effects (may affect up to 1 in 100 people):

- anaemia

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Riluzole

Keep this medicine out of the sight and reach of children.

HDPE containers: Store in the original package to protect from light. This medicinal product does not require any special temperature storage conditions.

Blisters: Store in the original package to protect from light. This medicinal product does not require any special temperature storage conditions.

Do not use this medicine after the expiry date, which is stated on the carton and the blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Riluzole contains

The active substance is riluzole.

Each Riluzole 50 mg Film-coated Tablet contains 50 mg of riluzole.

The other tablet ingredients are anhydrous calcium hydrogen phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate.

The film-coat ingredients are hypromellose, titanium dioxide (E171) and macrogol 400.

What Riluzole looks like and contents of the pack

Riluzole 50 mg Film-coated Tablets are white, film-coated, capsule shaped, biconvex tablets, debossed with 'M' on one side and 'RE 50' on the other side.

Riluzole 50 mg Film-coated Tablets come in blister packs of 14, 56, 60 and 112 tablets, perforated unit dose blisters of 56 x 1 tablets and plastic bottles containing 56, 112 and 250 tablets*.

*Not all pack sizes may be marketed

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

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