

Riluzole 50mg film-coated tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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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 nervous 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 Before you take

Do not take Riluzole if you

- are **allergic** (hypersensitive) to riluzole or any of the other ingredients of Riluzole tablets.
- have any **liver disease** or **increased blood levels of some enzymes** of the liver (transaminases).
- are **pregnant or breast-feeding**.

Take special care with Riluzole

Tell your doctor

- 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 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.

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

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

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

If you think you may be pregnant, or if you intend to breast-feed, ask your doctor for advice before taking Riluzole.

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

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 tablets than you should

If you have taken too many tablets, contact your doctor or the nearest hospital emergency department immediately.

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 product, ask your doctor or pharmacist.

4 Possible side effects

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

Important

You should stop taking Riluzole and see your doctor immediately if you experience symptoms of angioedema, such as

- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath.

Tell your doctor immediately 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.
- 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.
- cough or difficulties in breathing, as this may be a sign of **lung disease** (called interstitial lung disease).

Very common side effects (affects more than 1 user in 10):

- tiredness
- feeling sick
- increased blood levels of some enzymes of the liver (transaminases). Could be associated with jaundice, study data indicates that Asian patients may be more susceptible to liver function test abnormalities than Caucasian patients (see before you take).

Common side effects (affects 1 to 10 users in 100):

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

Uncommon side effects (affects 1 to 10 users in 1,000):

- allergic reactions, swelling of the face, lips, tongue or throat associated with difficulties in breathing and/or swallowing (angioedema)
- anaemia
- inflammation of the pancreas (pancreatitis).

} rare.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight of children. Do not use Riluzole after the expiry date which is stated on the carton and the blister. Keep the blister in the outer carton in order to protect from light. This medicinal product does not require any special temperature storage conditions.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Riluzole contains

- The active substance is riluzole. Each film-coated tablet contains 50mg of riluzole.
- The other ingredients are:
- Tablet core: calcium hydrogen phosphate, anhydrous; maize starch, pregelatinised; crosscarmellose sodium; silica, colloidal anhydrous; magnesium stearate.
- Tablet coating: OPADRY AMB white 03F28689 consisting of: hypromellose; macrogol 6000; titanium dioxide (E171).

What Riluzole looks like and contents of the pack

Riluzole tablets are white to off white, oval and biconvex film-coated tablets marked RL 50.

Pack sizes of 56 film-coated tablets

Marketing Authorisation Holder and Manufacturer

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Iceland

This leaflet was last revised in March 2012