

Riluzole 50mg film-coated tablets

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.

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1 What Riluzole Tablets are and what they are used for

What Riluzole Tablets are

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

What Riluzole Tablets are used for

Riluzole Tablets are 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 Tablets stop 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 Tablets

Do not take Riluzole Tablets if you:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Riluzole Tablets if:

- you have any **liver problems**: yellowing of your skin or the white of your eyes (jaundice), itching all over, feeling sick, being sick
- your **kidneys** are not working very well
- 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 Tablets is not recommended because there is no information available in this population.

Other medicines and Riluzole Tablets

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 Tablets if you are or think you may be pregnant, or if you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, 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.

This medicine contains less than 1 mmol sodium (23mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3 How to take Riluzole Tablets

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 orally, 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 take too many tablets, contact your doctor or the nearest hospital emergency department immediately.

If you forget to take Riluzole Tablets

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 stop taking Riluzole Tablets

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

Stop taking Riluzole Tablets and see your doctor immediately if you experience symptoms of a serious allergic reaction, such as:

- swelling of the face, lips, tongue and throat that can cause difficulty in breathing
- difficulty swallowing
- hives.

Tell your doctor immediately if you experience:

- **fever** (increase in temperature) because Riluzole Tablets 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 these may be signs of **liver disease** (hepatitis). Your doctor may do regular blood tests while you are taking Riluzole Tablets 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).

Other side effects:

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

- tiredness
- feeling sick
- increased blood levels of some enzymes of the liver (transaminases).

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

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

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

- anaemia
- inflammation of the pancreas (pancreatitis).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5 How to store Riluzole Tablets

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

Do not use this medicine 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.

Do not throw away 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 Tablets contain

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

What Riluzole Tablets look like and contents of the pack

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

Pack size of 56 film-coated tablets.

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Manufacturer

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