

PACKAGE LEAFLET

Package leaflet: Information for the user

Riluzole 50 mg 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.

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
5. How to store Riluzole
6. Contents of the pack and other information

1. What Riluzole is and what it is used for

What Riluzole is

The active substance in Riluzole 50 mg film-coated tablets 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 damage to the nerve cells responsible for sending instructions to the muscles lead to weakness, muscle wasting 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 taking **Riluzole**:

- if you have any **liver problems**: yellowing of your skin or the whites of your eyes (jaundice), itching all over, feeling sick, being sick
- if your **kidneys** are not working very well
- if you have any **fever** (sometimes this can be due to a low number of white blood cells which can lead to 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 because there is no information available in this population.

Other medicines and Riluzole

Tell your doctor 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 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 for advice before taking this medicine.

Driving and using machines

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

Riluzole contains sodium

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

3. How to take Riluzole

Always take this medicine exactly as your doctor 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.

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 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 whites 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).

Other side effects

Very common side effects (may affect more than 1 in 10 patients) of Riluzole are:

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

Common side effects (may affect up to 1 in 10 patients) of Riluzole are:

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

Uncommon side effects (may affect up to 1 in 100 patients) of Riluzole are:

- anaemia
- allergic reactions
- inflammation of the pancreas (pancreatitis).

Not known: frequency cannot be estimated from the available data

- rash.

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, 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

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. 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 film-coated tablet contains 50 mg riluzole.
- The other ingredients are:
Tablet core: calcium hydrogen phosphate anhydrous (E341), microcrystalline cellulose (E460), povidone (K-30) (E1201), croscarmellose sodium (E468), colloidal anhydrous silica (E551), talc, magnesium stearate (E572).
Tablet coating: opadry white 03B68903 consisting of hypromellose 6CP, titanium dioxide (E171), talc, macrogol 400.

What Riluzole looks like and content of the pack

The tablets are white to off white coloured, round shape, biconvex, film coated tablets debossed with '538' on one side and plain on the other side.

Riluzole is available in a pack of 56 or 98 tablets (4 or 7 blister cards of 14 tablets each) to be taken orally.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sun Pharmaceutical Industries Europe B.V.

Polarisavenue 87

2132 JH Hoofddorp

The Netherlands

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Germany: Riluzol SUN 50 mg Filmtabletten

Italy: Riluzolo SUN 50 mg compresse rivestite con film

Spain: Riluzol SUN 50 mg comprimidos recubiertos con película EFG

United Kingdom (NI): Riluzole 50 mg film-coated tablets

This leaflet was last revised in 11/2022.