

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### 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 50 mg film-coated tablets is and what it is used for
2. What you need to know before you take Riluzole 50 mg film-coated tablets
3. How to take Riluzole 50 mg film-coated tablets
4. Possible side effects
5. How to store Riluzole 50 mg film-coated tablets
6. Contents of the pack and other information

#### **1. What Riluzole 50 mg film-coated tablets is and what it is used for**

#### **What Riluzole 50 mg film-coated tablets are**

The active substance in Riluzole 50 mg film-coated tablets is riluzole which acts on the nervous system.

#### **What Riluzole 50 mg film-coated tablets are 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 50 mg film-coated tablets**

#### **Do not take Riluzole 50 mg film-coated tablets**

- 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 before taking Riluzole 50 mg film-coated 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
- 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 50 mg film-coated tablets is not recommended because there is no information available in this population.

#### **Other medicines and Riluzole 50 mg film-coated tablets:**

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

#### **Pregnancy, breast-feeding and fertility**

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 Riluzole 50 mg film-coated tablets**

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 50 mg film-coated 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 50 mg film-coated 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 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 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).

### **Other side effects**

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

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

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

[www.mhra.gov.uk/yellowcard](http://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 50 mg film-coated 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 after EXP:. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 50 mg film-coated tablets contains**

The active substance is riluzole.

Each film-coated tablet contains 50 mg of riluzole.

The other ingredients are:

**Core:** Calcium hydrogen phosphate anhydrous, Cellulose microcrystalline, Croscarmellose sodium, Silica colloidal anhydrous, Magnesium stearate;

**Coating:** Hypromellose, Titanium Dioxide (E171), Macrogol-400.

## **What Riluzole 50 mg film-coated tablets looks like and contents of the pack**

Riluzole 50 mg film-coated tablets are supplied as:

White to off-white, capsule shaped, bevelled edged film-coated tablets, engraved with '381' on one side and 'G' on other side.

Riluzole 50 mg film-coated Tablets are available in PVC/PVDC aluminium blisters of 28, 56, 98 film-coated tablets.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

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**This leaflet was last revised in January/2023**