Package leaflet: Information for the patient

Riluzol 1A Pharma® 50 mg, filmomhulde tabletten

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 [nationally completed name] is and what it is used for

What [nationally completed name] is

The active substance in [nationally completed name] is riluzole which acts on the nervous system.

What [nationally completed name] is used for

[nationally completed name] 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. [nationally completed name] 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 [nationally completed name]

Do not take [nationally completed name]:

- if you are **allergic** (hypersensitive) 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 [nationally completed name]

- 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 [nationally completed name] 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.

Other medicines and [nationally completed name]:

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 [nationally completed name] 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, or if you intend to breast-feed, 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.

[Nationally completed name] contains sodium:

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

3. How to take [nationally completed name]

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 [nationally completed name] than you should:

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

If you forget to take [nationally completed name]:
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 [nationally completed name] 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 [nationally completed name] 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).

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

- tiredness

- feeling sick

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

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

- dizziness

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

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

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

Not known: frequency that 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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, blister and bottle 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. Content of the pack and other information

What [nationally completed name] contains

- The active substance is riluzole. Each film-coated tablet contains 50 mg of riluzole.

- The other ingredients are calcium hydrogen phosphate anhydrous, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, silica, colloidal anhydrous, hypromellose, macrogol, titanium dioxide.

What [nationally completed name] looks like and contents of the pack

White to off-white, film-coated, capsule shaped tablet with 'RLZ' debossed on one side and plain on other side.

The tablets are packed in Alu/PVC blisters or in a HDPE bottle with a child-resistant closure.

Pack sizes:

Blister: 14, 28, 56, 60, 98 film-coated tablets

Bottle: 60 film-coated tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

1 A Pharma GmbH

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Duitsland

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Slovenië

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9220 Lendava

Slovenië

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39179 Barleben

Duitsland

S.C. Sandoz, S.R.L.

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RO-540472 Targu-Mures

Roemenië

In het register ingeschreven onder

Riluzol 1A Pharma 50 mg is in het register ingeschreven onder RVG 106640.

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen

Nederland: Riluzol 1A Pharma 50 mg, filmomhulde tabletten

Duitsland: Riluzol 1A Pharma 50 mg Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in januari 2023.