

Package leaflet: Information for the user

Riluzol Actavis 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 /.../ is and what it is used for
2. What you need to know before you take /.../
3. How to take /.../
4. Possible side effects
5. How to store /.../
6. Contents of the pack and other information

1. What /.../ is and what it is used for

What /.../ is

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

What /.../ is used for

/.../ 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. /.../ 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 /.../

Do not take /.../

- 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 /.../

- 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 /.../ is not recommended because there is no information available in this population.

Other medicines and /.../

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

Pregnancy and 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.

You **MUST NOT** take /.../ if you are or think you may be pregnant, or if you are breast feeding

Driving and using machines

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

/.../contains sodium

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

3. How to take /.../

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 /.../ than you should

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

If you forget to take /.../

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

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

- swelling of the face, lips, tongue or throat
- difficulties in swallowing
- hives and difficulties in breathing.

Tell your doctor immediately

- if you experience any **fever** (increase in temperature) because /.../ 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 /.../ 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 /.../ 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 /.../ are:

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

Uncommon side effects (may affect up to 1 in 100 people) of /.../ 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 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 /.../

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 blister and the carton after EXP. The expiry date refers to the last day of that month.

Blisters (aluminium/aluminium): This medicinal product does not require any special storage conditions.
Blisters (aluminium/PVC): 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 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 /.../ contains

- The active substance is riluzole. Each film-coated tablet contains 50 mg 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 /.../ looks like and contents of the pack

/.../ are white or off-white, oval and biconvex film-coated tablets marked RL 50 on one side.

Blister pack sizes of 28, 30, 56 and 60 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Iceland:	Riluzol Actavis
Norway:	Riluzol Actavis
Sweden:	Riluzol Actavis

This leaflet was last revised in
16-FEB-2023