

RILUTEK[®] TABLET

Riluzole (50 mg)

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What Rilutek is used for

- Rilutek is used to treat people with amyotrophic lateral sclerosis (ALS), which can cause muscle degeneration leading to muscle weakness. It is a form of Motor Neurone Disease. Please consult your doctor for more information about ALS and the reason why this medicine has been prescribed for you

How Rilutek works

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

- ALS is a form of motor neurone disease where attacks of the nerve cells responsible for sending instruction 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. Rilutek stops the release of glutamate and this may help in preventing the nerve cells being damaged.

Before you use Rilutek

When you must not use it

Do not take Rilutek

- if you are allergic (hypersensitive) to riluzole or any of the other ingredients of Rilutek,

- if you have any liver disease or increased blood levels of some enzymes of the liver (transaminases),

- if you are pregnant or breast-feeding.

Before you start to use it

Take special care with RILUTEK

Tell your doctor:

- 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
- the use of Rilutek is not recommended in children because there is no information available in this population.
- if you have lung disease

If any of the above applies to you, or if you are not sure, tell your doctor who will decide what to do

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and Rilutek may interfere with each other. These include:

- theophylline (a medicine used to treat asthma)
- amitriptyline (a medicine used to treat depression)
- some types of antibiotics eg. rifampicin and quinolones
- omeprazole (a medicine used to treat gastric ulcers)
- some medicines used to treat depression eg. Clomipramine and fluvoxamine
- diazepam (a medicine for sedation)
- diclofenac (a medicine used to reduce pain and inflammation)

These medicines may be affected by

Rilutek, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

Tell your doctor if you smoke and how much coffee you drink. Nicotine and caffeine may affect the amount of Rilutek in your body.

How to use Rilutek

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).

How much to use

Follow the directions given to you by your doctor and pharmacist carefully.

The recommended dose is one tablet, twice a day.

When to use it

Take Rilutek tablets at about the same time each day (e.g. in the morning and evening) unless your doctor tells you otherwise.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the medicine.

If you are not sure when to consume it, ask your doctor or pharmacist.

How long to use it

Continue taking your medicine for as long as your doctor tells you.

If you forget to use it

- 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 product, ask your doctor or pharmacist.

If you use too much (overdose)

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

While you are using it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Rilutek.

Pregnancy and breast-feeding

You **MUST NOT** take Rilutek 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 Rilutek.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Rilutek, or change the dosage, without checking with your doctor.

Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

RILUTEK contains sodium

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

Side Effect

Like all medicines, Rilutek can cause side effects, although not everybody gets them.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rilutek.

IMPORTANT

Tell your doctor immediately

- if you experience any fever (increase in temperature) because Rilutek 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 Rilutek 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 (affecting more than 1 in 10 patients) of Rilutek are:

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

Common side effects (affecting between 1 in 10 and 1 in 100 patients) of Rilutek are:

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

Uncommon side effects (affecting between 1 in 100 and 1 in 1000 patients) of Rilutek are:

- anaemia
- allergic reactions
- inflammation of the pancreas (pancreatitis)
- lung disease (called interstitial lung disease).

Not known: frequency cannot be estimated from the available data

- rash

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Other side effects not listed above may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Rilutek

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep out of the reach and sight of children.

Do not use Rilutek after the expiry date which is stated on the carton and the blister.

Disposal

If your doctor tells you to stop taking Rilutek or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Product Description

What it looks like

The tablets are film-coated, capsule-shaped and white. Each tablet contains 50 mg of riluzole and is engraved with "RPR 202" on one side.

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

Ingredients:

- The active substance is Riluzole.

- The other ingredients are:

Core: anhydrous dibasic calcium phosphate, micro crystalline cellulose, anhydrous colloidal silica, magnesium stearate, croscarmellose sodium;
Coating: hypromellose, macrogol 6000, titanium dioxide (E171).

MAL Numbers:

Rilutek Tablets 50mg:
MAL20051294AZ

Manufacturer and Product Registration Holder

Manufacturer

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Product Registration Holder

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