PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

RILUTEK 50 mg Film Coated Tablets

Active ingredient: Riluzole 50 mg

Inactive and allergenic ingredients in the preparation: see section 6 "Further information" and section 2 "Important information regarding some of the ingredients of the medicine".

Read the leaflet carefully in its entirety before using the medicine.

Keep this leaflet; you may need to read it again.

This leaflet contains concise information about the medicine.

If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The preparation is intended for the treatment of adults, from the age of 18 years.

1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of ALS (amyotrophic lateral sclerosis) – a motor neuron disease.

ALS is a type of neuronal disease that impairs transfer of information from the nerves to the muscles, which leads to weakness, muscle impairment and paralysis.

Therapeutic group: The substance acts on the central nervous system.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are **sensitive** (**allergic**) to the active ingredient or any of the additional ingredients contained in the medicine (see section 6 "Further Information").

You are suffering from a **liver disease** or from an increase in blood level of enzymes associated with liver function (transaminases).

You are **pregnant** or **breastfeeding.**

Special warnings regarding use of the medicine

Do not use the medicine without consulting a doctor before commencing treatment:

- If you are suffering from l**iver problems**: yellowing of the skin or the white part of the eyes (jaundice), itching all over the body, feeling sick or being sick.
- If your **kidneys** are not functioning well.
- If you have any **fever**: it can be due to low white blood cell count, which might cause an increased risk of infection.

Children and adolescents

If you are under 18 years of age, use of Rilutek is not recommended since there is no information in this population.

Tests and follow-up

During the treatment period with this medicine, perform liver function tests.

If, while taking the medicine, you suffer from a disease accompanied by fever, inform the doctor immediately.

Drug interactions

If you are taking, have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

CYP1A2 enzyme inhibitors such as: caffeine, diclofenac, diazepam, nicergoline, clomipramine, imipramine, fluvoxamine, phenacetin, theophylline, amitriptyline and quinolones.

CYP1A2 enzyme inducers such as: cigarette smoke, charcoal-broiled food, rifampicin, omeprazole.

Pregnancy and breastfeeding

Do not use the medicine if you are pregnant, think you are pregnant or are breastfeeding.

If you intend to breastfeed, consult the doctor before commencing use of Rilutek.

Driving and operating machinery

You can drive or operate machinery unless you feel dizzy after taking the medicine.

Important information regarding some of the ingredients of the medicine

Rilutek contains sodium. This medicine contains less than 1 mmol (23 mg) sodium per tablet; this means it is essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally one tablet, twice a day (every 12 hours).

Do not exceed the recommended dose.

Do not chew! Swallow the medicine with water.

The manufacturer has no information regarding the possibility of halving, pulverizing or crushing the tablets.

It is recommended to take the medicine one hour before, or two hours after, a meal.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the scheduled time, skip the forgotten dose and take the next dose at the usual time.

Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Rilutek may cause side effects in some users.

Do not be alarmed by the list of side effects. You may not suffer from any of them.

Important

Refer to a doctor immediately

- If you have any **fever**, since Rilutek can cause a decrease in the white blood cell count. The doctor may refer you for blood tests to check the number of white blood cells in your blood, which are important in fighting infection.
- Upon experiencing any of the following symptoms: yellowing of the skin or white part of the eyes (jaundice), itching all over the body, feeling sick or being sick; these can be signs of **liver disease**. The doctor may routinely send you for blood tests during treatment with the medicine.
- If you experience cough or difficulties in breathing – this may be a sign of lung disease.

Other side effects

Very common side effects (can affect more than one in ten people):

Tiredness, nausea, increased liver enzyme levels (transaminases).

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

Dizziness, sleepiness, headache, numbness/tingling of the mouth, rapid pulse, abdominal pain, vomiting, diarrhea, pain.

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

Anemia, allergic reactions, inflammation of the pancreas.

Side effects with unknown frequency (frequency cannot be estimated from the available data):

Rash.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: *https://sideeffects.health.gov.il/*

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

There are no special storage conditions. It is recommended to store at room temperature.

Store in the original package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Dibasic calcium phosphate anhydrous, Microcrystalline cellulose, Croscarmellose sodium, Hydroxypropylmethylcellulose (Hypromellose), Magnesium stearate, Colloidal silica anhydrous, Polyethylene glycol 6000 (macrogol 6000), Titanium dioxide.

What the medicine looks like and the contents of the package:

A package of 56 white tablets, with "RPR 202" engraved on them.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please refer to your doctor.

Registration Holder and Importer and address: sanofi-aventis Israel ltd., 10 Beni Gaon St., Netanya.

Revised in January 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 106-26-29046