Patient Information Leaflet for Rilutek Tablets

Please read this leaflet carefully before you start taking your **Rilutek Tablets**. This leaflet is a summary of the important information about your tablets. If you have any questions or are not sure about anything to do with your treatment, ask your doctor or pharmacist for more information.

Scheduling Status: **S4**

Proprietary Name:

RILUTEK Tablets

Composition:

Each tablet contains: Riluzole 50 mg

Rilutek Tablets also contain the following inactive ingredients:

Dibasic calcium phosphate, Microcrystalline cellulose, Colloidal silica, Magnesium stearate, Croscarmellose sodium, Hydroxymethyl cellulose, Polyethylene glycol, Titanium dioxide.

Indications:

Rilutek is indicated for the extension of survival of patients with the bulbar variant of motor neuron disease.

Before taking this medicine:

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice. If you are pregnant or breastfeeding your baby while taking this

medicine, please consult your doctor, pharmacist or other health care professional for advice

How to take this medicine:

The recommended daily dose in adults is 100 mg [50 mg (one tablet) every 12 hours]. Rilutek should be taken between mealtimes i.e. at least one hour before or two hours after a meal. No significant increased benefit can be expected from higher daily doses.

Contra-Indications:

Patients who have a history of severe hypersensitivity reactions to riluzole or any of the tablet components. Safety in pregnancy and lactation has not been demon-strated. Safety and effectiveness in any neurodegenerative process occurring in children or adolescents has not been established. Safety and effectiveness in patients with impaired Renal and Hepatic Function have not been conducted.

Special Warnings:

Elevations of alanine-aminotransferase (ALT) levels to more than 3 times the upper limit of the normal range (ULN) were observed in about 10 % of the patients treated with riluzole compared to 3.7 % in the placebo group; levels increased to more than 5 times the ULN in about 3 % of the patients treated with riluzole compared to 2 % of the placebo treated patients. The increases in ALT usually appeared within 3 months after the start of therapy with riluzole; they were usually transient and levels returned to below 2 times the ULN after 2 to 6 months while treatment was continued. These increases were rarely associated with jaundice. In patients with increases in ALT to more than 5 times the ULN, treatment was discontinued and the levels returned to less than 2 times the ULN within 2 to 4 months.

Riluzole should not be used in patients who have active liver disease. Patients should be warned about the potential for dizziness, vertigo or sleepiness, and advised not to drive or operate machinery if these symptoms occur.

Side-effects:

Not all side effects reported for this medicine are included in this leaflet. If your general state of health worsens while taking this medicine, please consult your doctor.

The most frequent side-effects related to riluzole were lack of energy, general malaise, nausea, vomiting, dizziness, diarrhoea, abdominal pain and other gastro-intestinal disturbances, vertigo, circumoral paraesthesia, anorexia, sleepiness, decreased lung function, pneumonia and elevated blood levels of some liver enzymes. Other side-effects may include skin disorders, pain, cardiovascular disorders, arthralgia, urinary disorders and headache.

Decreases in the number of white blood cells (which are important in fighting infections) may occur.

Special Precautions:

It is recommended that serum transaminases including ALT (some liver enzymes) be measured before and during therapy with riluzole. ALT should be measured every month during the first 3 months, of treatment, every 3 months during the remainder of the first year, and periodically thereafter. ALT levels should be measured frequently in patients who developed elevated ALT levels.

Riluzole should be discontinued if the ALT levels increase to five times the ULN.

There is no experience with dose reduction or rechallenge in patients who have developed an increase of ALT to 5 times ULN. Readministration of riluzole to patients in this situation cannot be recommended.

Decreases in the number of white blood cells (which are important in fighting infections) may occur. In case you experience fever (increase in temperature), you must call your doctor immediately.

Overdosage and Treatment:

There have been no reports of overdose with riluzole; no specific treatment information or antidote are available. In case of overdosage, treatment is symptomatic and supportive.

Storage and Disposal:

- Must be kept out of the reach of children.
- Do not share medicines prescribed for you with others.
- Rilutek tablets must be stored below 25 °C and protected from light.

Presentation:

Rilutek tablets are packaged in opaque PVC/Aluminium blister packs containing 56 tablets.

Identification:

Rilutek is a white capsule-shaped film coated tablet containing 50 mg of riluzole. Each tablet is engraved with “RPR 202 ” on one side of the tablet.

Registration Numbers:

30/34/0229

Name And Business Address Of Applicant:

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