PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RILUTEK 50 mg film-coated tablets

Riluzole

Sugar free.

Read all of this leaflet carefully before you start taking RILUTEK.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RILUTEK has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What RILUTEK is and what it is used for

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

2. What you need to know before you take RILUTEK

Do not take RILUTEK:

- if you are hypersensitive (allergic) to riluzole or any of the other ingredients of RILUTEK (listed in section 6)
- if you have any active liver disease
- if you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**)

Warnings and precautions

Take special care with RILUTEK:

- 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 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 experience cough or difficulties in breathing, as this may be a sign of lung disease (called interstitial lung disease).

Children and adolescents

The use of RILUTEK is not recommended in children or adolescents, because there is no information available in this population.

Other medicines and RILUTEK

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

RILUTEK with food and drink

RILUTEK should be taken between mealtimes i.e. at least one hour before or two hours after a meal.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking RILUTEK.

Driving and using machines

Take special care if you experience dizziness, vertigo (a sensation of spinning or dizziness) or sleepiness. Do not to drive a vehicle or operate machinery if any of these symptoms occur.
It is not always possible to predict to what extend RILUTEK may interfere with your daily activities. You should ensure that you do not engage in activities until you are aware of the measure to which RILTEK affects them.

RILUTEK contains sodium

RILUTEK contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially “sodium free”.

3. How to take RILUTEK

Do not share medicines prescribed for you with any other person.
Always take RILUTEK exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended daily dose in adults is 100 mg [this means 50 mg (one tablet), twice a day (every 12 hours)]. No significant increased benefit can be expected from higher daily doses.

Your doctor will tell you how long your treatment with RILUTEK will last. If you have the impression that the effect of RILUTEK is too strong or too weak, tell your doctor or pharmacist.

If you take more RILUTEK than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take RILUTEK

If you forget to take your RILUTEK 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 forgotten individual doses.

If you have any further questions on the use of RILUTEK, ask your doctor or pharmacist.

4. Possible side effects

RILUTEK can have side effects.

Not all side effects reported for RILUTEK are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RILUTEK, please consult your health care provider for advice.

If any of the following happens, stop taking RILUTEK and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RILUTEK. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heart disorders, such as an increase in heart rate (tachycardia)

- chest pain (angina)
- 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.
- anaphylactoid reaction (a severe, potentially life-threatening allergic reaction)
- coma (deep state of unconsciousness where a person is unable to wake up or respond)
- 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.
- coughing or difficulties in breathing, decreased lung function (called interstitial lung disease or pneumonia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Very common side effects:

- nausea (feeling sick)
- abnormal liver function tests
- asthenia (lack of energy).

Common side effects:

- headache
- dizziness
- numbness or tingling of the mouth (circumoral paraesthesia)
- sleepiness
- vertigo (sensation of spinning or dizziness)
- diarrhoea
- abdominal (stomach) pain
- vomiting (being sick)

- anorexia (decreased appetite)
- pain
- increased blood levels of some enzymes of the liver.

Uncommon side effects:

- a blood disorder called anaemia (low levels of red blood cells), characterised by unusual tiredness, irregular heartbeat, chest pain, pale skin or shortness of breath
- weight loss
- amnesia (memory loss)
- depression
- muscle stiffness and difficulty moving
- high blood pressure
- a sudden drop in blood pressure when you stand up from a sitting or lying position (causing dizziness or light-headedness)
- inflammation of the pancreas (pancreatitis)
- inflammation of the colon (colitis)
- inflammation and sores inside the mouth (stomatitis)
- inflammation of the lining of your belly or stomach area (peritonitis)
- rectal disorders (conditions affecting the anus and rectum area)
- a severe bacterial infection in your intestines, characterised by diarrhoea (pseudomembranous *enterocolitis*)
- peptic ulcer haemorrhage (a bleeding sore in your stomach or small intestine)
- dyspepsia (heartburn or indigestion)
- flatulence (passing gas)
- oral moniliasis (oral thrush)
- eczema (a skin condition that causes dry, itchy and inflamed)
- nail disorder (discolouration, pitting, ridges and changes in nail thickness or growth)
- hair loss (temporary)
- exfoliative dermatitis (a severe skin condition, causing extreme shedding of the top layers of

your skin)

- joint pain (arthralgia)
- urinary disorders, such as urinary tract infection or painful urination (dysuria)
- back pain
- malaise (general feeling of discomfort or lack of well-being).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of RILUTEK.

Side effects can be reported directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

5. How to store RILUTEK

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C.
- Protect from light.

6. Contents of the pack and other information

What RILUTEK contains

The active substance is riluzole 50 mg per film-coated tablet.

The other ingredients are dibasic calcium phosphate, microcrystalline cellulose, colloidal silica, magnesium stearate, croscarmellose sodium, hypromellose, macrogol 6000, titanium dioxide (E171).

What RILUTEK looks like and contents of the pack

White capsule-shaped film-coated tablet containing 50 mg riluzole. Each tablet is engraved with "RPR 202" on one side of the tablet.

Opaque PVC/Aluminium blister packs containing 56 tablets.

Holder of Certificate of Registration

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