PART III: CONSUMER INFORMATION

[Pr]RILUTEK®
(riluzole)

This leaflet is part III of a three-part "Product Monograph" published when RILUTEK was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RILUTEK. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

The treatment of amyotrophic lateral sclerosis (ALS), a disease of the brain and spinal cord that causes muscle weakness and wasting, and eventually paralysis.

What it does:

RILUTEK is not a cure for ALS; although it may prolong life by an average time of about 3 months.

There is no evidence that RILUTEK has an effect on the symptoms of ALS, so you are not likely to feel a difference or see a noticeable change in your condition during treatment.

When it should not be used:

- if you have liver problems
- if you have an allergy or sensitivity to riluzole or any of the other tablet ingredients (See "**What the nonmedicinal ingredients are**" in this section)
- if you are pregnant or breastfeeding

What the medicinal ingredient is:
Riluzole

What the nonmedicinal ingredients are:

anhydrous colloidal silica, anhydrous dibasic calcium phosphate, croscarmellose sodium, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 6000 and titanium dioxide.

What dosage forms it comes in:
Film-Coated Tablets, 50 mg

WARNINGS AND PRECAUTIONS

Some people may experience liver injury while taking RILUTEK that is most often mild and temporary. Your doctor should periodically test the function of your liver while you are taking RILUTEK. Depending on these tests results, your doctor may decide that additional liver evaluation is required. Signs of liver injury for patients to watch for are listed in the section "**SIDE EFFECTS AND WHAT TO DO ABOUT THEM"**

BEFORE you use RILUTEK talk to your doctor or pharmacist if:

- if you have ever had any allergic reactions to medications, food etc.
- you have liver problems
- you are taking other drugs that may be toxic to the liver
- you are or think you are pregnant or if you may become pregnant
- you are breastfeeding

Because RILUTEK can, rarely, decrease white blood cells counts, let your doctor know if you experience fever, so the decision can be made as to whether further investigation is needed.

RILUTEK may make you to feel dizzy or sleepy. If you experience these feelings do not drive a vehicle or use machinery.

RILUTEK must not be given to anyone other than the person for whom it was prescribed.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with RILUTEK include:

- Drugs that may be toxic to the liver, such as allopurinol, methyldopa or sulfasalazine.

- Drugs or substances that may have an effect on the elimination of RILUTEK from the body, such as caffeine, the antibiotics quinolones and rifampicin, theophylline, amitriptyline, omeprazole, cigarette smoke and charcoal-broiled food.

PROPER USE OF THIS MEDICATION

Usual dose:

The effect of RILUTEK therapy is dependent upon taking it continuously at regular intervals, as directed. It is important that you follow your doctor's instructions about taking RILUTEK.

The recommended dose is 1 tablet (50 mg) every 12 hours.

RILUTEK should be taken 1 hour before meals or 2 hours after meals. You should take this medicine on a regular basis and at the same time of the day (e.g., in the morning and evening) each day.

Overdose:

There is no benefit in increasing the dose above two tablets per day. In fact, you may experience more side effects. Any medication taken in excess can have serious consequences.

If you have taken too much RILUTEK, immediately see your doctor or go to your nearest hospital emergency department. Show the doctor your bottle of tablets. Do this even if there are no signs of discomfort or poisoning.

Missed Dose:

If you miss or skip a dose of RILUTEK, take your medicine at the next scheduled time. Do not take any extra tablets to make up for those you missed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects are mild, temporary liver injury, weakness, fatigue, dizziness and stomach upset. Some less common side effects are: vomiting, mouth sores, increase or loss of appetite, eczema, diarrhea, irregular or fast heart beat and swelling of the hands, feet or legs. RILUTEK may have other side effects which have not been described here. If you notice any change in your health while taking RILUTEK, tell your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Dizziness	√		
	Fatigue	√		
	Stomach upset	√		
	Weakness	√		
Uncommon	Depressed mood		√	
	Diarrhea		√	
	Eczema		√	
	Fever		√	
	Irregular or fast heart beat		√	
	Loss of appetite		√	
	Mouth sores		√	
	Signs of possible liver problems (with symptoms such as: dark urine, a yellow discoloring of the skin or sclera (the white of your eye), itchiness, nausea, vomiting, loss of appetite, general discomfort, tiredness, or abdominal swelling)			√
	Swelling of hands, feet or legs		√	
	Vomiting		√	
	Respiratory problems (dry cough, and/or difficulty in breathing)			√

This is not a complete list of side effects. For any unexpected effects while taking RILUTEK, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at: www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

RILUTEK should be stored at room temperature (15 to 30°C) and protected from bright light.

RILUTEK must be kept out of the reach of children.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.sanofi-aventis.ca or by contacting the sponsor, sanofi-aventis Canada Inc. at: 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last revised: May 11, 2010