

PART III: CONSUMER INFORMATION

MYLAN-RILUZOLE
(Riluzole Tablets, USP)
50 mg

This leaflet is part III of a three-part “Product Monograph” published when MYLAN-RILUZOLE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MYLAN-RILUZOLE. 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:

MYLAN-RILUZOLE is not a cure for ALS; although it may prolong life by an average time of about 3 months. There is no evidence that riluzole 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:

Calcium hydrogen phosphate anhydrous, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, microcrystalline cellulose. Coating: hydroxypropyl methylcellulose, polyethylene glycol 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 MYLAN-RILUZOLE that is most often mild and temporary. Your doctor should periodically test the function of your liver while you are taking MYLAN-RILUZOLE. 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 section “**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**”.

BEFORE you use MYLAN-RILUZOLE talk to your doctor or pharmacist 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 riluzole 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.

MYLAN-RILUZOLE may make you feel dizzy or sleepy. If you experience these feelings do not drive a vehicle or use machinery.

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

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with MYLAN-RILUZOLE include:

- Drugs that may be toxic to the liver, such as allopurinol, methyl dopa or sulfasalazine.
- Drugs or substances that may have an effect on the elimination of MYLAN-RILUZOLE 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 MYLAN-RILUZOLE therapy is dependent upon taking it continuously at regular intervals, as directed. It is important that you follow your doctor’s instructions about taking MYLAN-RILUZOLE.

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

MYLAN-RILUZOLE 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 MYLAN-RILUZOLE, 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.

For management of a suspected drug overdose, contact your health care practitioner, hospital emergency department, or regional Poison Control Centre immediately.

Missed Dose:

If you miss or skip a dose of MYLAN-RILUZOLE, 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. MYLAN-RILUZOLE may have other side effects which have not been described here. If you notice any change in your health while taking MYLAN-RILUZOLE, 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 seek immediate emergency medical attention |
|----------|--|-------------------------------------|--------------|---|
| | | 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 discolouring 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 MYLAN-RILUZOLE, 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 0701E
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, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

MYLAN-RILUZOLE should be stored in well-closed, light resistant containers at controlled room temperature (15°C to 30°C).

MYLAN-RILUZOLE must be kept out of the reach of children.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information leaflet plus the full Monograph, prepared for health professionals can be obtained at www.mylan.ca or by contacting the sponsor, Mylan Pharmaceuticals ULC at: 1-800-575-1379.

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