

**CONSUMER INFORMATION**  
**Product Monograph Part III**

**LYRICA\***

**pregabalin**

**25, 50, 75, 100, 150, 200, 225, 300 mg pregabalin, capsules**

**Pfizer Canada Inc.**

**Submission Control No. 088400**

The Consumer Information Section (Part III) of the Product Monograph for LYRICA has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on June 2, 2005 and does not necessarily reflect the most current information for the product.

**For the most up-to-date product information, please consult your health care professional.**

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

## PART III: CONSUMER INFORMATION

### LYRICA\* pregabalin

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

### ABOUT THIS MEDICATION

#### What the medication is used for:

LYRICA is a prescription medicine used for the symptomatic relief of neuropathic pain associated with

- Diabetic peripheral neuropathy (pain from damaged nerves due to diabetes)
- Postherpetic neuralgia (persisting pain following healing of the rash due to shingles)

#### What it does:

LYRICA can relieve pain and it may help some patients sleep better. Some patients taking LYRICA showed improvement as early as the first week of treatment.

#### When it should not be used:

You should not take LYRICA if you are allergic to pregabalin, the main ingredient in LYRICA, or any other ingredient in LYRICA (see "What the important non-medicinal ingredients are"). Children under the age of 18 years.

#### What the medicinal ingredient is:

pregabalin

#### What the important nonmedicinal ingredients are:

The non-medicinal ingredients that make up the capsule core are lactose monohydrate, corn starch and talc.

The capsule shells contain gelatin and titanium dioxide. In addition, the orange capsule shells contain red iron oxide and the white capsule shells contain sodium lauryl sulfate and colloidal silicon dioxide.

The markings on the capsules are in black ink, which contains shellac, black iron oxide, propylene glycol, potassium hydroxide and water.

#### What dosage forms it comes in:

Capsules containing 25, 50, 75, 150, or 300 mg of pregabalin.

### WARNINGS AND PRECAUTIONS

BEFORE you use LYRICA tell your doctor or pharmacist if:

- you are taking any other prescription or nonprescription medicines, or natural/herbal remedies
- you have any kidney problems
- you are pregnant, plan to become pregnant, think you might be pregnant, or are breast feeding
- have ever had an allergic reaction (itching, wheezing, hives, or swelling of the throat or face) to any medicine.

### INTERACTIONS WITH THIS MEDICATION

While you are taking LYRICA, don't start any new medicines, including natural or herbal medicines, without talking to your doctor first. Your doctor or pharmacist will know which medicines are safe for you to take together. LYRICA does not interfere with birth control pills.

### PROPER USE OF THIS MEDICATION

You can take LYRICA with or without food. Avoid alcoholic drinks while taking LYRICA.

#### Usual adult dose:

Your doctor will tell you how much to take and when to take it.

#### Overdose:

Call your doctor or poison control center, or go to the nearest emergency room

#### Missed Dose:

If you miss a dose by a few hours, take it as soon as you remember. If it is close to your next dose, do NOT take the missed capsules. Simply wait and restart LYRICA with your next scheduled dose.

Do not suddenly stop taking LYRICA. Talk to your doctor first. Plan ahead to have a refill so you don't run out.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Some patients may have side effects while taking LYRICA. Side effects are usually mild. In studies, few patients stopped taking LYRICA due to side effects.

The most common side effects were: dizziness, sleepiness, blurred vision, dry mouth, swelling of the extremities, weight gain, and trouble concentrating.

When you start LYRICA, you may get sleepy or experience dizziness. Avoid potentially hazardous tasks: do not drive a car or operate machinery, until you are sure that this medication does not affect your ability to drive or operate machinery or until you get used to LYRICA.

**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	√		
	Sleepiness	√		
	Blurred vision		√	
Uncommon	Weight gain	√		
	Swelling of hands and feet (edema)		√	

This leaflet was prepared by Pfizer Canada Inc.

Pfizer Canada Inc.

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This is not a complete list of side effects. If you have any unexpected effects while taking LYRICA, contact your doctor or pharmacist.

**HOW TO STORE IT**

Keep LYRICA out of reach of children. Store it at room temperature (15°C to 30°C) in the package it came in.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: [cadrmp@hc-sc.gc.ca](mailto:cadrmp@hc-sc.gc.ca)

By regular mail:  
 National AR Centre  
 Marketed Health Products Safety and Effectiveness  
 Information Division  
 Marketed Health Products Directorate  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

**MORE INFORMATION**

This document plus the full Product Monograph, prepared for health professionals can be found at:

<http://www.pfizer.ca>

or by contacting the sponsor, Pfizer Canada Inc., at:

1-800-463-6001

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