

## PART III: CONSUMER INFORMATION

### Pr LYRICA® Pregabalin Capsules

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 is the most important information I should know about LYRICA?

1. LYRICA may cause serious allergic reactions. Call your doctor right away if you think you have any of the following symptoms of a serious allergic reaction:

- swelling of the face, mouth, lips, gums, tongue or neck
- have any trouble breathing
- other allergic reactions may include rash, hives and blisters.

2. LYRICA may cause dizziness and sleepiness.

- Do not drive a car, work with machines, or do other dangerous activities until you know how LYRICA affects how alert you are. Ask your doctor when it is okay to do these activities.

3. LYRICA may cause problems with your eyesight, including blurry vision. Call your doctor if you have any changes in your eyesight.

##### 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 rash due to shingles)
- Pain from damaged nerves in the spinal cord
- LYRICA is also used for the symptomatic relief of pain associated with fibromyalgia (a condition which includes widespread pain).

##### What it does:

LYRICA can relieve pain. 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 non-medicinal ingredients are"). Children under the age of 18 years.

##### What the medicinal ingredient is:

Pregabalin

##### What the nonmedicinal ingredients are:

The non-medicinal ingredients that make up the capsule core are corn starch, lactose monohydrate, 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 colloidal silicon dioxide and sodium lauryl sulphate.

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

##### What dosage forms it comes in:

Capsules containing 25, 50, 75, 100, 150, 200, 225 or 300 mg of pregabalin.

#### WARNINGS AND PRECAUTIONS

##### **SERIOUS WARNINGS AND PRECAUTIONS**

Taking LYRICA with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

BEFORE you use LYRICA tell your doctor or pharmacist if:

- you are taking any other prescription medicines including narcotic pain medicines like oxycodone, nonprescription medicines, or natural/herbal remedies.
- you have any kidney problems.
- you are pregnant, plan to become pregnant, or think you might be pregnant.
- you are breastfeeding. LYRICA passes into breast milk and it is not known if it can harm your baby. You and your healthcare provider should discuss whether you should take LYRICA or breast-feed, but you should not do both.
- you have ever had an allergic reaction (itching, wheezing, hives, or swelling of the throat or face) to pregabalin or any of the nonmedicinal ingredients listed in "What the nonmedicinal ingredients are".
- you have a history of heart disease called congestive heart failure.
- you have a history of lower gastrointestinal problems (e.g., constipation, blocked or paralysed bowel), or you are taking medication(s) that may cause constipation.

**Pregnancy Registry:** If you become pregnant while taking LYRICA, talk to your doctor about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of anticonvulsant medicines during pregnancy. Any woman who is currently pregnant and is taking antiepileptic drugs for any reason, can enroll in the registry. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>.

### 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.

You may have a higher chance for dizziness and sleepiness if the following drugs are taken with LYRICA:

- Alcohol
- Medicines for anxiety (such as lorazepam)
- Narcotic pain medicine (such as oxycodone)
- Any medicines that make you sleepy

You may have a higher chance of weight gain or swelling if the antidiabetic pills, Avandia (rosiglitazone) or Actos (pioglitazone) are taken with LYRICA.

### 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:**

**In case of a drug overdose, immediately go to the nearest emergency room even if you do not feel sick. Make sure you take your medicine bottle with you to show the doctor.**

#### **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, trouble concentrating, lack of energy, muscle weakness, constipation, and forgetfulness.

A small number of patients taking a drug of this type may experience thoughts of suicide. Your doctor should be informed immediately if this occurs.

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.

When LYRICA is taken with other medications that may cause constipation (such as opioid pain medications), it is possible that gastrointestinal problems may occur (e.g., constipation, blocked or paralysed bowel).

### 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 emergency medical assistance
		Only if severe	In all cases	
Common	Dizziness	√		
	Sleepiness	√		
	Blurred vision		√	
Uncommon	Weight gain	√		
	Swelling of hands and feet (edema)		√	
	Swelling of the face, mouth, lips, gums, neck or throat, trouble breathing			√
	Extreme fatigue		√	
	Increased cough		√	

**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 emergency medical assistance
	Only if severe	In all cases	
Allergic reactions (skin rash, hives, blisters)			√
Decrease in the amount of urine		√	
Thoughts of suicide		√	
Very rare	Seizures		√

This leaflet was prepared by Upjohn Canada ULC

Last revised: May 11, 2020

Upjohn Canada ULC  
Kirkland, Québec H9J 2M5

® C.P. Pharmaceuticals International C.V.  
Upjohn Canada ULC, Licensee  
© Upjohn Canada ULC, 2020

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 Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**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, Upjohn Canada ULC at:

1-800-463-6001