

## PATIENT INFORMATION



(LEER- i- kah)

Read the Patient Information that comes with LYRICA before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment. If you have any questions about LYRICA, ask your doctor or pharmacist.

### **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 is LYRICA?**

LYRICA is a prescription medicine used in adults, 18 years and older, to treat:

- pain from damaged nerves (neuropathic pain) that happens with diabetes
- pain from damaged nerves (neuropathic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection)
- partial seizures when taken together with other seizure medicines
- fibromyalgia

LYRICA has not been studied in children under 18 years of age.

#### Pain from Damaged Nerves (neuropathic pain)

Diabetes and shingles can damage your nerves. Pain from damaged nerves may feel sharp, burning, tingling, shooting, or numb. If you have diabetes, the pain

can be in your arms, hands, fingers, legs, feet, or toes. If you have shingles, the pain is in the area of your rash. You may experience this kind of pain even with a very light touch. LYRICA can help relieve the pain. Some people taking LYRICA had less pain by the end of the first week of LYRICA therapy. LYRICA may not work for everyone.

### Partial Seizures

Partial seizures start in one part of the brain. A seizure can make you fearful, confused, or just feel "funny". You may smell strange smells. A seizure may cause your arm or leg to jerk or shake. It can spread to other parts of your brain, make you pass out, and cause your whole body to start jerking.

LYRICA can lower the number of seizures for people who are already taking seizure medicine.

### Fibromyalgia

Fibromyalgia is a condition which includes widespread muscle pain and difficulty performing daily activities. LYRICA can help relieve the pain and improve function. Some people taking LYRICA had less pain by the end of the first week of LYRICA therapy. LYRICA may not work for everyone.

### **Who Should Not Take LYRICA?**

**Do not take LYRICA if you are allergic to any of its ingredients.** The active ingredient is pregabalin. See the end of this leaflet for a complete list of ingredients in LYRICA.

### **What should I tell my doctor before taking LYRICA?**

**Tell your doctor about all your medical conditions, including if you:**

- **have any kidney problems or get kidney dialysis**
- **have heart problems including heart failure**
- **have a bleeding problem or a low blood platelet count**
- **are pregnant or plan to become pregnant.** It is not known if LYRICA may harm your unborn baby. You and your doctor will have to decide if LYRICA is right for you while you are pregnant.
- **are breastfeeding.** It is not known if LYRICA passes into breast milk and if it can harm your baby. You and your doctor should decide whether you should take LYRICA or breastfeed, but not both.

**Tell your doctor about all the medicines you take including prescription or non- prescription medicines, vitamins or herbal supplements.** LYRICA and other medicines may affect each other. Especially tell your doctor if you take:

- **angiotensin converting enzyme (ACE) inhibitors.** You may have a higher chance for swelling and hives if these medicines are taken with LYRICA. See "What is the most important information I should know about LYRICA?"

- Avandia® (rosiglitazone) or Actos® (pioglitazone) for diabetes. You may have a higher chance of weight gain or swelling if these medicines are taken with LYRICA. See "What are the possible side effects of LYRICA."
- any narcotic pain medicine (such as oxycodone), tranquilizers or medicines for anxiety (such as lorazepam). You may have a higher chance for dizziness and sleepiness if these medicines are taken with LYRICA. See "What is the most important information I should know about LYRICA?"
- any medicines that make you sleepy

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine.

**Tell your doctor if you plan to father a child.** Animal studies showed that pregabalin, the active ingredient in LYRICA, made male animals less fertile and caused sperm abnormalities. Also, in animal studies, birth defects occurred in the offspring of male animals who were treated with pregabalin. It is not known if these effects would happen in people.

#### **How should I take LYRICA?**

- Take LYRICA exactly as prescribed. Your doctor may adjust your dose during treatment. Do not change your dose without talking to your doctor.
- Do not stop taking LYRICA suddenly without talking to your doctor. If you stop taking LYRICA suddenly, you may have headaches, nausea, diarrhea or trouble sleeping. Talk with your doctor about how to slowly stop LYRICA.
- LYRICA is usually taken 2 or 3 times a day, depending on your medical condition. Your doctor will tell you how much LYRICA to take and when to take it. Take LYRICA at the same times each day.
- LYRICA may be taken with or without food.
- If you miss a dose by a few hours, take it as soon as you remember. If it is close to your next dose, just take LYRICA at your next regular time. **Do not** take two doses at the same time.
- If you take too much LYRICA, call your doctor or poison control center or go to the nearest emergency room right away.

#### **What Should I Avoid While Taking LYRICA?**

- **Do not drive a car, work with machines, or do other dangerous activities until you know how LYRICA affects how alert you are.** See "What is the most important information I should know about LYRICA?"
- **Do not drink alcohol while taking LYRICA.** LYRICA and alcohol can affect each other and increase side effects such as sleepiness and dizziness. This can be dangerous.

**Do not take other medicines without talking to your doctor.** Other medicines include prescription and non-prescription medicines, vitamins, and herbal supplements. LYRICA and other medicines may affect each other and increase the side effects of swelling, sleepiness and dizziness. Be especially

careful about medicines that make you sleepy (such as sleeping pills, anxiety medicines, tranquilizers and some antihistamines, pain relievers and seizure medicines).

### **What are the possible side effects of LYRICA?**

#### **LYRICA may cause side effects including:**

- **allergic reactions.** See "What is the most important information I should know about LYRICA?"
- **weight gain and swelling of the hands and feet (edema).** Weight gain may affect the management of diabetes. Weight gain and swelling can also be a serious problem for people with heart problems.
- **dizziness and sleepiness.** See "What is the most important information I should know about LYRICA?"
- **eyesight problems.** See "What is the most important information I should know about LYRICA?"
- **unexplained muscle problems, such as muscle pain, soreness, or weakness.** If you develop these symptoms, especially if you also feel sick and have a fever, tell your doctor right away.

#### **The most common side effects of LYRICA are:**

- dizziness
- blurry vision
- weight gain
- sleepiness
- trouble concentrating
- swelling of hands and feet
- dry mouth

LYRICA caused skin sores in animals. Although skin sores were not seen in studies in people, if you have diabetes, you should pay extra attention to your skin while taking LYRICA and tell your doctor of any sores or skin problems.

LYRICA may cause some people to feel "high." Tell your doctor, if you have abused prescription medicines, street drugs, or alcohol in the past.

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the side effects of LYRICA. For more information, ask your doctor or pharmacist.

#### **How should I store LYRICA?**

- Store LYRICA at room temperature, 59 to 86° F (15 to 30° C) in its original package.
- Safely throw away LYRICA that is out of date or no longer needed.
- **Keep LYRICA and all medicines out of the reach of children.**

#### **General information about LYRICA**

Medicines are sometimes prescribed for conditions other than those listed in patient information leaflets. Do not use LYRICA for a condition for which it was not prescribed. Do not give LYRICA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about LYRICA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about LYRICA that is written for health professionals.

You can also visit the LYRICA website at [www. LYRICA. com](http://www.LYRICA.com) or call 1- 866-4LYRICA.

### **What are the ingredients In LYRICA?**

**Active ingredient:** pregabalin

**Inactive ingredients:** lactose monohydrate, cornstarch, talc;

**Capsule shell:** gelatin and titanium dioxide; Orange capsule shell: red iron oxide; White capsule shell: sodium lauryl sulfate, colloidal silicon dioxide. Colloidal silicon dioxide is a manufacturing aid that may or may not be present in the capsule shells.

**Imprinting ink:** shellac, black iron oxide, propylene glycol, potassium hydroxide.

Manufactured by:  
Pfizer Pharmaceuticals LLC  
Vega Baja, PR 00694



LAB-0299-5.0

Avandia is a registered trademark of GlaxoSmithKline.

Actos is a registered trademark of Takeda Chemicals Industries, Ltd. and used under license by Takeda Pharmaceuticals of America, Inc. and Eli Lilly and Co.

June 2007