

MEDICATION GUIDE

LYRICA (LEER-i-kah)

(pregabalin)

Capsules and Oral Solution, CV

Read this Medication Guide before you start taking LYRICA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about LYRICA, ask your healthcare provider or pharmacist.

What is the most important information I should know about LYRICA?

1. LYRICA may cause serious, even life-threatening, allergic reactions.

Stop taking LYRICA and call your healthcare provider right away if you have any of these signs of a serious allergic reaction:

- swelling of your face, mouth, lips, gums, tongue, throat or neck
- trouble breathing
- rash, hives (raised bumps) or blisters

2. Like other antiepileptic drugs, LYRICA may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

If you have suicidal thoughts or actions, do not stop LYRICA without first talking to a healthcare provider.

- Stopping LYRICA suddenly can cause serious problems.
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

3. LYRICA may cause swelling of your hands, legs and feet. This swelling can be a serious problem for people with heart problems.

4. 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 you. Ask your healthcare provider about when it will be okay to do these activities.

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
- partial seizures when taken together with other seizure medicines
- fibromyalgia (pain all over your body)

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

Who Should Not Take LYRICA?

Do not take LYRICA if you are allergic to pregabalin or any of the ingredients in LYRICA.

See “What is the most important information I should know about LYRICA?” for the signs of an allergic reaction.

See the end of this leaflet for a complete list of ingredients in LYRICA.

What should I tell my healthcare provider before taking LYRICA?

Before taking LYRICA, tell your healthcare provider about all your medical conditions, including if you:

- have or have had depression, mood problems or suicidal thoughts or behavior

- have kidney problems or get kidney dialysis
- have heart problems including heart failure
- have a bleeding problem or a low blood platelet count
- have abused prescription medicines, street drugs, or alcohol in the past
- have ever had swelling of your face, mouth, tongue, lips, gums, neck, or throat (angioedema)
- plan to father a child. Animal studies have shown that pregabalin, the active ingredient in LYRICA, made male animals less fertile and caused sperm to change. Also, in animal studies, birth defects were seen in the offspring (babies) of male animals treated with pregabalin. It is not known if these problems can happen in people who take LYRICA.
- **are pregnant or plan to become pregnant. It is not known if LYRICA will harm your unborn baby.** You and your healthcare provider will have to decide if you should take LYRICA while you are pregnant. If you become pregnant while taking LYRICA, talk to your healthcare provider 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 antiepileptic drugs during pregnancy.
- **are breastfeeding. It is not known if LYRICA passes into breast milk and 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

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

- angiotensin converting enzyme (ACE) inhibitors, which are used to treat many conditions, including high blood pressure. 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), Avandamet (contains rosiglitazone and metformin), or Actos (pioglitazone) for diabetes. You may have a higher chance of weight gain or swelling of your hands or feet 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.
- any medicines that make you sleepy

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine. Do not start a new medicine without talking with your healthcare provider.

How should I take LYRICA?

- Take LYRICA exactly as prescribed. Your healthcare provider 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.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Do not stop taking LYRICA without talking to your healthcare provider. If you stop taking LYRICA suddenly you may have headaches, nausea, diarrhea, trouble sleeping, increased sweating, or you may feel anxious. If you have epilepsy and you stop taking LYRICA suddenly, you may have seizures more often. Talk with your healthcare provider about how to stop LYRICA slowly.
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not take two doses at the same time.**
- If you take too much LYRICA, call your healthcare provider 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 you.**
- **Do not drink alcohol while taking LYRICA.** LYRICA and alcohol can affect each other and increase side effects such as sleepiness and dizziness.

What are the possible side effects of LYRICA?

LYRICA may cause serious side effects, including:

- See "What is the most important information I should know about LYRICA?"
- **muscle problems, muscle pain, soreness, or weakness.** If you have these symptoms, especially if you feel sick and have a fever, tell your healthcare provider right away.
- **problems with your eyesight, including blurry vision.** Call your healthcare provider if you have any changes in your eyesight.
- **weight gain.** If you have diabetes, weight gain may affect the management of your diabetes. Weight gain can also be a serious problem for people with heart problems.

- **feeling “high”**

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 animal studies. Skin sores did not happen in studies in people. If you have diabetes, you should pay attention to your skin while taking LYRICA and tell your healthcare provider about any sores or skin problems.

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

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LYRICA?

- Store LYRICA capsules and oral solution at room temperature, 59°F to 86°F (15°C to 30°C) in its original package.
- LYRICA Oral Solution **must be used** within 45 days of first opening the bottle.
- Safely throw away any 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 purposes other than those listed in a Medication Guide. 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 Medication Guide summarizes the most important information about LYRICA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about LYRICA that is written for health professionals.

You can also visit the LYRICA website at www.LYRICA.com or call 1-866-459-7422 (1-866-4LYRICA).

What are the ingredients In LYRICA?

Active ingredient: pregabalin

Inactive ingredients:

LYRICA capsules: 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.

LYRICA oral solution: methylparaben, propylparaben, monobasic sodium phosphate anhydrous, dibasic sodium phosphate anhydrous, sucralose, artificial strawberry #11545 and purified water.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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