

Medication Guide

Pregabalin (pree-GAH-ba-lin) Capsules, CV

Read this Medication Guide before you start taking pregabalin 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 pregabalin, ask your healthcare provider or pharmacist.

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

Pregabalin may cause serious side effects including:

- serious, even life-threatening, allergic reactions
- swelling of your hands, legs and feet
- suicidal thoughts or actions
- dizziness and sleepiness
- serious breathing problems

These serious side effects are described below:

• Serious, even life-threatening, allergic reactions.

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

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

• Like other antiepileptic drugs, pregabalin 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:

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

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

- o Stopping pregabalin suddenly can cause serious problems.
- o 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.
- **Serious breathing problems** can occur when pregabalin is taken with other medicines that can cause severe sleepiness or decreased awareness, or when it is taken by someone who already has breathing problems. Watch for increased sleepiness or decreased breathing when starting pregabalin or when the dose is increased. Get help right away if breathing problems occur.
- **Swelling of your hands, legs and feet.** This swelling can be a serious problem for people with heart problems.
- **Dizziness and sleepiness.** Do not drive a car, work with machines, or do other dangerous activities until you know how pregabalin affects you. Ask your healthcare provider about when it will be okay to do these activities.

What is pregabalin?

Pregabalin is a prescription medicine used in adults, 18 years of age 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
- fibromyalgia (pain all over your body)
- pain from damaged nerves (neuropathic pain) that follows spinal cord injury

It is not known if pregabalin is safe and effective in people under 18 years of age for the treatment of fibromyalgia and neuropathic pain with diabetes, shingles, or spinal cord injury.

Pregabalin is a prescription medicine used in people 17 years of age and older to treat:

- partial-onset seizures when taken together with other seizure medicines.

For the treatment of partial-onset seizures when taken together with other seizure medicines, it is not known if pregabalin is safe and effective in children under 1 month of age.

Who should not take pregabalin?

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

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

See the end of this Medication Guide for a complete list of ingredients in pregabalin.

What should I tell my healthcare provider before taking pregabalin?

Before taking pregabalin, 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 breathing problems
- 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 pregabalin, 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 pregabalin.
- **are pregnant or plan to become pregnant. Pregabalin may harm your unborn baby.** You and your healthcare provider will have to decide if you should take pregabalin while you are pregnant.
 - If you become pregnant while taking pregabalin, 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. Information about the registry can also be found at the web site, <http://www.aedpregnancyregistry.org/>.
- **are breastfeeding or plan to breastfeed. Pregabalin passes into your breast milk. It is not known if pregabalin can harm your baby.** Talk to your healthcare provider about the best way to feed your baby if you take pregabalin. Breastfeeding is not recommended while taking pregabalin. **Breastfeeding is not recommended while taking pregabalin.**

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins or herbal supplements. Pregabalin 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 pregabalin.
- Avandia (rosiglitazone) 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 pregabalin.
- any opioid pain medicine (such as oxycodone), or medicines for anxiety (such as lorazepam) or insomnia (such as zolpidem). You may have a higher chance for dizziness, sleepiness or serious breathing problems if these medicines are taken with pregabalin.
- 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 pregabalin?

- Take pregabalin exactly as prescribed. Your healthcare provider will tell you how much pregabalin to take and when to take it.
- Pregabalin 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 pregabalin without talking to your healthcare provider. If you stop taking pregabalin suddenly you may have headaches, nausea, diarrhea, trouble sleeping, increased sweating, or you may feel anxious. If you have epilepsy and you stop taking pregabalin suddenly, you may have seizures more often. Talk with your healthcare provider about how to stop pregabalin 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 pregabalin, call your healthcare provider or poison control center, or go to the nearest emergency room right away.

What should I avoid while taking pregabalin?

- **Do not drive a car, work with machines, or do other dangerous activities until you know how pregabalin affects you.**
- **Do not drink alcohol while taking pregabalin.** Pregabalin and alcohol can affect each other and increase side effects such as sleepiness and dizziness.

What are the possible side effects of pregabalin?

Pregabalin may cause serious side effects, including:

- See "What is the most important information I should know about pregabalin?"
- **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 pregabalin in adults are:

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

The most common side effects of pregabalin in children are weight gain, increase in appetite, and sleepiness.

Pregabalin 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 pregabalin 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 pregabalin. 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 1800-FDA-1088.

How should I store pregabalin?

- Store pregabalin capsule at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature) in its original package.
- Safely throw away any pregabalin that is out of date or no longer needed.

Keep pregabalin and all medicines out of the reach of children.

General information about the safe and effective use of pregabalin

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use pregabalin for a condition for which it was not prescribed. Do not give pregabalin to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about pregabalin that is written for health professionals.

For more information call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in pregabalin?

Active ingredient: pregabalin

Inactive ingredients: corn starch and talc

The capsule shells contain gelatin and titanium dioxide. In addition, the orange capsule shells contain red iron oxide which is used in 50 mg, 75 mg, 100 mg, 200 mg, 225 mg and 300 mg strength of pregabalin capsules. The imprinting ink contains shellac, propylene glycol, black iron oxide, and potassium hydroxide.

Pediatric use information is approved for Pfizer's LYRICA (pregabalin) Capsules and Oral Solution products. However, due to Pfizer's marketing exclusivity rights, this drug product is not labeled with that pediatric information.

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

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Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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