

MEDICATION GUIDE
PREGABALIN [pree gab' a lin]
EXTENDED-RELEASE
TABLETS, CV
Rx Only

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

What is the most important information I should know about pregabalin extended-release tablets?

Pregabalin extended-release tablets may cause serious side effects including:

- **Serious, even life-threatening, allergic reactions**
- **Suicidal thoughts or actions**
- **Serious breathing problems**
- **Swelling of your hands, legs and feet**
- **Dizziness and sleepiness**

These serious side effects are described below:

- **Serious, even life-threatening, allergic reactions.**

Stop taking pregabalin extended-release tablets 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
- skin redness
- **Pregabalin extended-release tablets 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 pregabalin extended-release tablets without first talking to a healthcare provider.

- Stopping pregabalin extended-release tablets 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.
- **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 extended-release tablets affects you. Ask your healthcare provider about when it will be okay to do these activities.

What are pregabalin extended-release tablets?

Pregabalin extended-release tablets are prescription medicine used to treat:

- pain from damaged nerves (neuropathic pain) that happens with diabetes
- pain from damaged nerves (neuropathic pain) that follows healing of shingles

It is not known if pregabalin extended-release tablets are safe and effective in children.

It is not known if pregabalin extended-release tablets are effective when used for the treatment of fibromyalgia, or when taken with other seizure medicines for adults with partial onset seizures.

Who Should Not Take pregabalin extended-release tablets?

Do not take pregabalin extended-release tablets if you are allergic to pregabalin or any of the ingredients in pregabalin extended-release tablets.

See “What is the most important information I should know about pregabalin extended-release tablets?” for the signs of an allergic reaction. See the end of this leaflet for a complete list of ingredients in pregabalin extended-release tablets.

What should I tell my healthcare provider before taking pregabalin extended-release tablets?

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

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins or herbal supplements. Pregabalin extended-release tablets 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 extended-release tablets. See "What is the most important information I should know about pregabalin extended-release tablets?"
- 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 pregabalin extended-release tablets. See "What are the possible side effects of pregabalin extended-release tablets."
- 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 extended-release tablets.
- 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 extended-release tablets?

- Take pregabalin extended-release tablets exactly as prescribed. Your healthcare provider will tell you how much pregabalin extended-release tablets to take and when to take it.
- Take pregabalin extended-release tablets at the same time each day.
- Pregabalin extended-release tablets must be taken **after** your evening meal. Swallow the tablet whole and do not split, crush or chew the tablet.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Do not stop taking pregabalin extended-release tablets without talking to your healthcare provider. If you stop taking pregabalin extended-release tablets suddenly you may have headaches, nausea, diarrhea, trouble sleeping, or you may feel anxious. If you have epilepsy, are taking pregabalin extended-release tablets for pain, and stop taking pregabalin extended-release tablets suddenly, you may have seizures more often. Talk with your healthcare provider about how to stop pregabalin extended-release tablets slowly.
- If you miss a dose after your evening meal, take it prior to bedtime following a snack. If you miss the dose prior to bedtime, then take it following your morning meal. If you do not take the dose the following morning, then take the next dose at your regular time after your evening meal. **Do not take 2 doses at the same time.**
- If you take too much pregabalin extended-release tablets, call your healthcare provider or poison control center, or go to the nearest emergency room right away.

What should I avoid while taking pregabalin extended-release tablets?

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

What are the possible side effects of pregabalin extended-release tablets?

Pregabalin extended-release tablets may cause serious side effects, including:

- **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 extended-release tablets are:

- dizziness
- blurry vision
- weight gain
- sleepiness
- fatigue (tiredness)
- swelling of hands and feet
- dry mouth
- nausea

Pregabalin extended-release tablets 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 extended-release tablets 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 extended-release tablets. 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 pregabalin extended-release tablets?

- Store pregabalin extended-release tablets at room temperature between 68° F to 77° F (20° C to 25° C) in its original package.
- Safely throw away any pregabalin extended-release tablets that is out of date or no longer needed.

Keep pregabalin extended-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of pregabalin extended-release tablets.

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

For more information, call 1-800-406-7984

What are the ingredients in pregabalin extended-release tablets?

Active ingredient: Pregabalin

Inactive ingredients: carbomer homopolymer, crospovidone, FD&C blue no. 2, FD & C red no. 40, FD&C yellow no. 6, hypromellose, magnesium stearate, methacrylic acid copolymer type C, polyethylene glycol, polyvinyl alcohol (part. hydrolysed), sodium bicarbonate and talc.

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