

MEDICATION GUIDE

Gabapentin (gab" a pen' tin) Tablets USP

Read the Medication Guide before you start taking gabapentin 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.

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

Do not stop taking gabapentin without first talking to your healthcare provider.

Stopping gabapentin suddenly can cause serious problems.

Gabapentin can cause serious side effects including:

1. Like other antiepileptic drugs, gabapentin 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

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.

Do not stop taking gabapentin without first talking to a healthcare provider.

- Stopping gabapentin suddenly can cause serious problems. Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

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.

2. **Changes in behavior and thinking** - Using gabapentin in children 3 to 12 years of age can cause emotional changes, aggressive behavior, problems with concentration, restlessness, changes in school performance, and hyperactivity.

What is gabapentin?

Gabapentin is a prescription medicine used to treat:

- Pain from damaged nerves (postherpetic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection) in adults.
- Partial seizures when taken together with other medicines in adults and children 3 years of age and older.

Who should not take gabapentin?

Do not take gabapentin tablets if you are allergic to gabapentin or any of the other ingredients in gabapentin tablets. See the end of this Medication Guide for a complete list of ingredients in gabapentin tablets.

What should I tell my healthcare provider before taking gabapentin?

Before taking gabapentin, tell your healthcare provider if you:

- have or have had kidney problems or are on hemodialysis
- have or have had depression, mood problems, or suicidal thoughts or behavior
- are pregnant or plan to become pregnant. It is not known if gabapentin can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking gabapentin. You and your healthcare provider will decide if you should take gabapentin while you are pregnant.
 - If you become pregnant while taking gabapentin, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy. You can enroll in this registry by calling 1-888-233-2334.
- are breast-feeding or plan to breast-feed. Gabapentin can pass into breast milk. You and your healthcare provider should decide how you will feed your baby while you take gabapentin.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking gabapentin with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take gabapentin?

- Take gabapentin exactly as prescribed. Your healthcare provider will tell you how much gabapentin to take.
 - Do not change your dose of gabapentin without talking to your healthcare provider. If you break a tablet in half the unused half of the tablet should be taken at your next scheduled dose. Half tablets not used within several days of breaking should be thrown away.
- Gabapentin can be taken with or without food. If you take an antacid containing aluminum and magnesium, such as Maalox[®], Mylanta[®], Gelusil[®], Gaviscon[®], or Di-Gel[®], you should wait at least 2 hours before taking your next dose of gabapentin.
- If you take too much gabapentin, call your healthcare provider or your local Poison Control Center right away.

What should I avoid while taking gabapentin?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking gabapentin without first talking with your healthcare provider. Taking gabapentin with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how gabapentin affects you. Gabapentin can slow your thinking and motor skills.

What are the possible side effects of gabapentin?

- See “What is the most important information I should know about gabapentin?”
- **The most common side effects of gabapentin include:**
 - dizziness
 - lack of coordination
 - viral infection
 - feeling drowsy
 - feeling tired
 - fever
 - jerky movements
 - difficulty with speaking
 - temporary loss of memory (amnesia)
 - tremor
 - difficulty with coordination
 - double vision
 - unusual eye movement

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

These are not all the possible side effects of gabapentin. 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 gabapentin?

- Store Gabapentin Tablets USP between 59°F to 86°F (15°C to 30°C).

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

General information about the safe and effective use of gabapentin

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use gabapentin for a condition for which it was not prescribed. Do not give gabapentin to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about gabapentin. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about gabapentin that was written for healthcare professionals.

For more information about gabapentin, go to www.glenmarkgenerics.com. For medical inquiries or to report side effects regarding gabapentin, please call 1 (888)721-7115.

What are the ingredients in gabapentin?

Active ingredient: gabapentin USP

Inactive ingredients in the tablets: corn starch, copovidone, poloxamer 407, magnesium stearate, polyethylene glycol, talc, hypromellose, titanium dioxide, macrogol, polysorbate 80 and purified water.

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

Manufactured by:

Glenmark Generics Ltd.

Colvale-Bardez, Goa 403 513, India

Manufactured for:



glenmark

Glenmark Generics Inc., USA

Mahwah, NJ 07430

Questions? 1 (888)721-7115

www.glenmarkgenerics.com

June 2011