MEDICATION GUIDE
GABAPENTIN TABLETS, USP
600 mg and 800 mg

Read the Medication Guide before you start taking gabapentin 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.

What is the most important information I should know about gabapentin tablets? Do not stop taking gabapentin tablets without first talking to your healthcare provider.

Stopping gabapentin suddenly can cause serious problems.

Gabapentin tablets can cause serious side effects including:

1. **Like other antiepileptic drugs, gabapentin 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

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 tablets 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 tablets 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 are gabapentin tablets?

Gabapentin tablets are 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 tablets?

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 tablets?

Before taking gabapentin tablets, 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 tablets can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking gabapentin tablets. You and your healthcare provider will decide if you should take gabapentin tablets while you are pregnant.
  - If you become pregnant while taking gabapentin tablets, 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 tablets can pass into breast milk. You and your healthcare provider should decide how you will feed your baby while you take gabapentin tablets.

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

Taking gabapentin tablets 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 tablets?

- Take gabapentin tablets exactly as prescribed. Your healthcare provider will tell you how much gabapentin to take.
  - Do not change your dose of gabapentin tablets 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 tablets 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 tablets.
- 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 tablets?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking gabapentin tablets without first talking with your healthcare provider. Taking gabapentin tablets with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

What are the possible side effects of gabapentin tablets?

- See “What is the most important information I should know about gabapentin tablets?”
- The most common side effects of gabapentin tablets include:
  - dizziness
  - difficulty with speaking
  - lack of coordination
  - temporary loss of memory (amnesia)
  - viral infection
  - tremor
  - feeling drowsy

- difficulty with coordination
- feeling tired
- double vision
- fever
- unusual eye movement
- jerky movements

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 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 gabapentin tablets?

- Store gabapentin tablets at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

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

General information about the safe and effective use of gabapentin tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use gabapentin tablets for a condition for which it was not prescribed. Do not give gabapentin tablets 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 tablets. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about gabapentin tablets that was written for healthcare professionals.

For medical inquiries or to report side effects regarding gabapentin tablets, please call Mylan Pharmaceuticals at 1-877-446-3679 (1-877-4-INFO-RX).

What are the ingredients in gabapentin tablets?

Active ingredient: gabapentin

Inactive ingredients in the tablets: crospovidone, hydroxpropyl cellulose, magnesium stearate, mannitol, poloxamer 407 and talc.

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

*Trademarks are the property of their respective owners.

Manufactured in India by:
Matrix Laboratories Limited
Secunderabad — 500 003, India
Code No. MH/DRUGS/25/NKD/89

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Distributed by:
UDL Laboratories, Inc.
Rockford, IL 61103

S-11002
1/11