

## MEDICATION GUIDE

### **Gabapentin (GA-be-PEN-tin) Oral Solution**

Read the Medication Guide before you start taking gabapentin oral solution 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 oral solution? Do not stop taking gabapentin oral solution without first talking to your healthcare provider.**

Stopping gabapentin oral solution suddenly can cause serious problems.

**Gabapentin oral solution can cause serious side effects including:**

**1. Suicidal Thoughts. Like other antiepileptic drugs, gabapentin oral solution 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 oral solution without first talking to a healthcare provider.**

- Stopping gabapentin oral solution 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 oral solution in children 3 to 12 years of age can cause emotional changes, aggressive behavior, problems with concentration, restlessness, changes in school performance, and hyperactivity.

**3. Gabapentin oral solution may cause serious or life-threatening allergic reactions** that may affect your skin or other parts of your body such as your liver or blood cells. This may cause you to be hospitalized or to stop gabapentin oral solution. You may or may not have a rash with an allergic reaction caused by gabapentin oral solution. Call a healthcare provider right away if you have any of the following symptoms:

- skin rash

- hives
- difficulty breathing
- fever
- swollen glands that do not go away
- swelling of your face, lips, throat, or tongue
- yellowing of your skin or of the whites of the eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- unexpected muscle pain
- frequent infections

These symptoms may be the first signs of a serious reaction. A healthcare provider should examine you to decide if you should continue taking gabapentin oral solution.

### **What is gabapentin oral solution?**

Gabapentin oral solution 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 with seizures.

### **Who should not take gabapentin oral solution?**

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

### **What should I tell my healthcare provider before taking gabapentin oral solution?**

#### **Before taking gabapentin oral solution, 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
- have diabetes
- are pregnant or plan to become pregnant. It is not known if gabapentin oral solution can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking gabapentin oral solution. You and your healthcare provider will decide if you should take gabapentin oral solution while you are pregnant.
  - If you become pregnant while taking gabapentin oral solution, 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 oral solution.

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

Taking gabapentin oral solution 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 oral solution?**

- Take gabapentin oral solution exactly as prescribed. Your healthcare provider will tell you how much gabapentin oral solution to take.

- Do not change your dose of gabapentin oral solution without talking to your healthcare provider.
- Gabapentin oral solution can be taken with or without food. If you take an antacid containing aluminum and magnesium, such as Maalox<sup>®</sup>, Mylanta<sup>®</sup>, Gelusil<sup>®</sup>, Gaviscon<sup>®</sup>, or Di-Gel<sup>®</sup>, you should wait at least 2 hours before taking your next dose of gabapentin oral solution.

If you take too much gabapentin oral solution, call your healthcare provider or your local Poison Control Center right away at 1-800-222-1222.

#### **What should I avoid while taking gabapentin oral solution?**

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking gabapentin oral solution without first talking with your healthcare provider. Taking gabapentin oral solution 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 oral solution affects you. Gabapentin oral solution can slow your thinking and motor skills.

#### **What are the possible side effects of gabapentin oral solution?**

##### **Gabapentin oral solution may cause serious side effects including:**

See “What is the most important information I should know about gabapentin oral solution?”

- problems driving while using gabapentin oral solution. See “What I should avoid while taking gabapentin oral solution?”
- sleepiness and dizziness, which could increase the occurrence of accidental injury, including falls
- **The most common side effects of gabapentin oral solution include:**
  - lack of coordination
  - viral infection
  - feeling drowsy
  - nausea and vomiting
  - difficulty with speaking
  - tremor
  - swelling, usually of legs and feet
  - feeling tired
  - fever
  - jerky movements
  - 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 oral solution. 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 oral solution?**

- Store gabapentin oral solution in the refrigerator between 36°F to 46°F (2°C to 8°C).

**Keep gabapentin oral solution and all medicines out of the reach of children.**

#### **General information about the safe and effective use of gabapentin oral solution**

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

For more information go to [www.amneal.com](http://www.amneal.com). or call 1-877-835-5472.

### **What are the ingredients in gabapentin oral solution?**

**Active ingredient:** gabapentin, USP

**Inactive ingredients in the oral solution:** acesulfame potassium, carboxymethylcellulose sodium, magnasweet, peppermint flavor, potassium sorbate and strawberry anise artificial flavor. Sodium hydroxide or hydrochloric acid may be added for adjustment of pH.

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

This product's label may have been updated. For current full prescribing information, please visit [www.amneal.com](http://www.amneal.com)

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