

MEDICATION GUIDE
Gabapentin Oral Solution
(gab-ah-PEN-tin)

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. Suicidal Thoughts. Like other antiepileptic drugs, gabapentin may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. This can happen while you take gabapentin as well as after stopping gabapentin.

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, changes in school performance, restlessness, and hyperactivity.

3. Gabapentin 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 taking gabapentin. You may or may not have a rash with an allergic reaction caused by gabapentin. 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.

4. Serious breathing problems. Serious breathing problems can happen when gabapentin is taken with other medicines (such as opioid medicines) that can cause severe sleepiness or decreased awareness, or when it is taken by someone who already has breathing problems. Call your healthcare provider or get medical help right away if you have any of the following symptoms:

- feel short of breath
- feel very tired
- dizziness
- breathing slower than normal
- confusion
- headache

Be sure that your caregiver or family members know which symptoms may be serious so they can call your healthcare provider or get medical help if you are unable to seek treatment on your own. Your healthcare provider may lower your dose or stop your treatment with gabapentin if you have serious breathing problems.

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.

It is not known if gabapentin is safe and effective to treat:

- children with pain from damaged nerves from a painful rash caused by the chicken pox virus.
- partial seizures in children under 3 years of age.

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.

Before taking gabapentin, tell your healthcare provider about all of your medical conditions including 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 a history of drug abuse
- have diabetes
- Have breathing problems
- 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.
 - **Pregnancy Registry:** 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 over-the-counter medicines, vitamins, and herbal supplements

Especially tell your healthcare provider if you take:

- any opioid pain medicine such as morphine, hydrocodone, oxycodone, or buprenorphine.
- any medicines for anxiety (such as lorazepam) or insomnia (such as zolpidem), or any medicines that make you sleepy. You may have a higher chance for dizziness, sleepiness, or breathing problems if these medicines are taken with gabapentin.

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 Oral Solution?

- 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.
- **Do not** stop taking gabapentin without talking to your healthcare provider first. If you stop taking gabapentin suddenly, you may develop side effects.
- Gabapentin Oral Solution 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. In case of overdose, get medical help or contact a live Poison Center expert right away at 1-800-222-1222. Advice is also available online at poisonhelp.org.

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 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?

Gabapentin may cause serious side effects including:

- See "What is the most important information I should know about gabapentin?"
- problems driving while using Gabapentin Oral Solution. See "What I should avoid while taking gabapentin?"
- sleepiness and dizziness, which could increase your chance of having an accidental injury, including falls

The most common side effects of Gabapentin Oral Solution include:

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| • lack of coordination | • feeling drowsy |
| • viral infection | • nausea and vomiting |
| • | • jerky movements |
| • difficulty with speaking | • difficulty with coordination |
| • tremor | • double vision |
| • swelling, usually of legs and feet | • unusual eye movement |

- feeling tired
- fever

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 Oral Solution?

- Store Gabapentin Oral Solution in the refrigerator between 36°F to 46°F (2°C to 8°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. You can ask your pharmacist or healthcare provider for information about gabapentin that is written for healthcare professionals.

For more information go to <http://www.acellapharma.com>. or call 1-800-541-4802.

What are the ingredients in Gabapentin Oral Solution?

Active ingredient: gabapentin

Inactive ingredients in the oral solution: anise flavor, artificial strawberry flavor, glycerin, hydrochloric acid, purified water, sodium hydroxide and xylitol.

Manufactured for: Acella Pharmaceuticals,

For more information go to www.acellapharma.com or call 1-800-541-4802

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.acellapharma.com

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