

MEDICATION GUIDE

NEURONTIN (Neu rŏn' tĭn)
(Gabapentin)

Capsules, Tablets, and Oral Solution

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

Stopping NEURONTIN suddenly can cause serious problems.

NEURONTIN can cause serious side effects including:

- 1. Like other antiepileptic drugs, NEURONTIN 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 NEURONTIN without first talking to a healthcare provider.

- Stopping NEURONTIN 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 NEURONTIN 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. NEURONTIN may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalized or to stop NEURONTIN. Call a healthcare provider right away if you have any of the following symptoms:

- skin rash
- hives
- fever
- swollen glands that do not go away
- swelling of your lip and 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 NEURONTIN.

What is NEURONTIN?

NEURONTIN 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 NEURONTIN?

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

What should I tell my healthcare provider before taking NEURONTIN?

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

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

Taking NEURONTIN 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 NEURONTIN?

- Take NEURONTIN exactly as prescribed. Your healthcare provider will tell you how much NEURONTIN to take.
 - Do not change your dose of NEURONTIN 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. If taking capsules, always swallow them whole with plenty of water.
- NEURONTIN 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 NEURONTIN.
- If you take too much NEURONTIN, call your healthcare provider or your local Poison Control Center right away.

What should I avoid while taking NEURONTIN?

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

What are the possible side effects of NEURONTIN?

- See "What is the most important information I should know about NEURONTIN?"
- **The most common side effects of NEURONTIN 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 NEURONTIN. 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 NEURONTIN?

- Store NEURONTIN Capsules between 59°F to 86°F (15°C to 30°C).
- Store NEURONTIN Tablets between 59°F to 86°F (15°C to 30°C).
- Store NEURONTIN Oral Solution in the refrigerator between 36°F to 46°F (2°C to 8°C).

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

General information about the safe and effective use of NEURONTIN

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

For more information about NEURONTIN, go to <http://www.pfizer.com>. For medical inquiries or to report side effects regarding NEURONTIN, please call 1-800-438-1985.

What are the ingredients in NEURONTIN?

Active ingredient: gabapentin

Inactive ingredients in the capsules: lactose, cornstarch, and talc.

The 100-mg capsule shell also contains: gelatin and titanium dioxide.

The 300-mg capsule shell also contains: gelatin, titanium dioxide, and yellow iron oxide.

The 400-mg capsule shell also contains: gelatin, red iron oxide, titanium dioxide, and yellow iron oxide. The imprinting ink contains FD&C Blue No. 2 and titanium dioxide.

Inactive ingredients in the tablets: poloxamer 407, copolyvidonum, cornstarch, magnesium stearate, hydroxypropyl cellulose, talc, candelilla wax, and purified water.

Inactive ingredients in the oral solution: glycerin, xylitol, purified water, and artificial flavor.

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



LAB-0397-2.0
June 2011