

**GABAPENTIN- gabapentin capsule**  
**Aphena Pharma Solutions - Tennessee, LLC**

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**MEDICATION GUIDE**

**Gabapentin Capsules, USP**

**Gabapentin Tablets, USP**

**(gab'' a 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.**

**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.

**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 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.

#### **What is gabapentin?**

Gabapentin is a prescription medicine used to treat:

- 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?**

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

#### **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
- have diabetes
- 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.

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 take gabapentin tablets and break a tablet in half, the unused half of the tablet should be taken at your next scheduled dose. Half tablets not used within 28 days of breaking should be thrown away.
  - Take gabapentin capsules with water.
- Gabapentin tablets 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.

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

### **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?**

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

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

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

- tremor
- unusual eye movement
- swelling, usually of legs and feet

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 capsules and tablets between 68°F to 77°F (20°C to 25°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 call ScieGen Pharmaceuticals, Inc. at 1-855-724-3436.

### **What are the ingredients in gabapentin capsules, USP?**

**Active ingredient:** gabapentin, USP

**Inactive ingredients in the capsules:** Pregelatinized starch (maize), lactose monohydrate, and talc.

The 100-mg capsule shell also contains: gelatin, titanium dioxide, and FD&C Blue 2.

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

The 400-mg capsule shell also contains: gelatin, titanium dioxide, ferric oxide yellow, and FD&C Blue 2.

The imprinting ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, and potassium hydroxide.

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

All brands listed are the trademarks of their respective owners.

### **HOW SUPPLIED**

100 mg Capsules (White/White colored, size '3' hard gelatin capsules with "103" printed on body of capsules containing white to off white granular powder) Bottles of 100 & 500

### **HOW SUPPLIED**

300 mg Capsules (Yellow/Yellow colored, size '1' hard gelatin capsules with "104" printed on body of capsules containing white to off white granular powder) Bottles of 100 & 500

### **HOW SUPPLIED**

400 mg Capsules (Orange/Orange colored, size '0' hard gelatin capsules with "105" printed on body of

capsules containing white to off white granular powder) Bottles of 100 & 500

## Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

Count	300 mg
60	71610-088-53
90	71610-088-60
180	71610-088-80
270	71610-088-92
360	71610-088-94

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

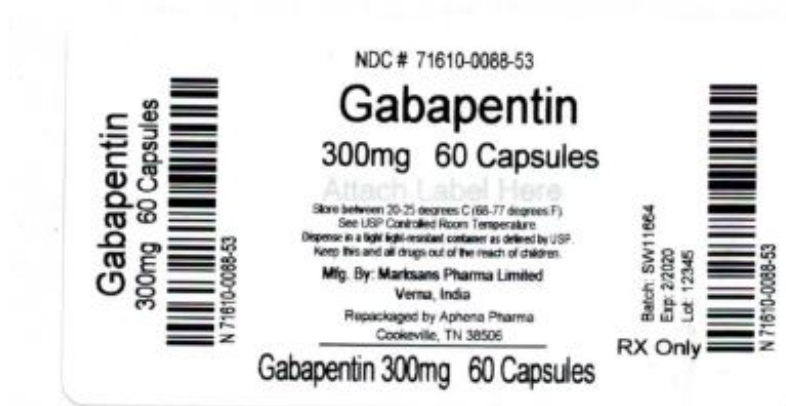


Cookeville, TN 38506

20180712JH

## PRINCIPAL DISPLAY PANEL - 300 mg

NDC 71610-088 - Gabapentin 300 mg - Rx Only



## GABAPENTIN

gabapentin capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:71610-088(NDC:49483-606)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GABAPENTIN (UNII: 6CW7F3G59X) (GABAPENTIN - UNII:6CW7F3G59X)	GABAPENTIN	300 mg

### Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	capsule	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	104
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-088-53	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2018	
2	NDC:71610-088-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2018	
3	NDC:71610-088-80	180 in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2018	
4	NDC:71610-088-92	270 in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2018	
5	NDC:71610-088-94	360 in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090007	12/30/2015	

**Labeler** - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

### Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-088)

Revised: 7/2018

Aphena Pharma Solutions - Tennessee, LLC