

GABAPENTIN- gabapentin capsule

NuCare Pharmaceuticals, Inc.

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)

NDC 68071-5017-1 BOTTLES OF 100

MEDICATION GUIDE

Gabapentin (gab' a pen' tin) Capsules
Read the Medication Guide before you start taking gabapentin capsules 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 capsules?
Gabapentin capsules without first talking to your healthcare provider.

Do not stop taking gabapentin capsules suddenly can cause serious problems.

Gabapentin capsules can cause serious side effects including:

1. **Suicidal Thoughts.** Like other antiepileptic drugs, gabapentin capsules may cause suicidal thoughts or actions in a very small number of people, about 1 in 100. If you have any of these symptoms, especially if they are new, worse, or worry you:

- 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
 - 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 capsules without first talking to a healthcare provider.

Stopping gabapentin capsules 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).

2. **Changes in behavior and thinking.** Using gabapentin capsules 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 capsules may cause a serious or life-threatening allergic reaction** that may affect your skin or other parts of your body such as your eyes or blood cells. This may cause you to be hospitalized or to stop gabapentin capsules. You may or may not have a rash with an allergic reaction caused by gabapentin capsules. Call a healthcare provider right away if you have any of the following symptoms:

How should I take gabapentin capsules?

- Take gabapentin capsules exactly as prescribed. Your healthcare provider will tell you how much gabapentin capsules to take.
 - Do not change your dose of gabapentin capsules without talking to your healthcare provider.
 - Take gabapentin capsules with plenty of water.
- Gabapentin capsules can be taken with or without food. If you take an antacid containing aluminum and magnesium, such as Maalox[®], Mylanta[®], Gelulac[®], Gavicon[®], or Di-Gel[®], you should wait at least 2 hours before taking your next dose of gabapentin capsules.

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

What should I avoid while taking gabapentin capsules?

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

What are the possible side effects of gabapentin capsules?

See "What is the most important information I should know about gabapentin capsules?"

Problems driving while using gabapentin capsules. See "What I should avoid while taking gabapentin capsules?"

Sleepiness and dizziness which could increase the occurrence of accidental injury, including falls

The most common side effects of gabapentin capsules include:

- lack of coordination
- feeling tired
- 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 capsules. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to Time-Cap Labs, Inc. at 1-877-376-4271 and/or the FDA at 1-800-FDA-1088.

How should I store gabapentin capsules?

Store gabapentin capsules between 68°F to 77°F (20°C to 25°C). Keep gabapentin capsules and all medicines out of the reach of children.

General information about the safe and effective use of gabapentin capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use gabapentin capsules for a condition for which it was not intended. Do not give gabapentin capsules to other people, even if they have the same symptoms that you have. It may harm them.

- skin rash
- blurred vision
- difficulty breathing
- fever
- enlarged glands that do not go away
- swelling of your face, lips, throat or tongue
- swelling of your skin or of the whites of the eyes
- unusual bruising or bleeding
- unusual 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 capsules.

What are gabapentin capsules?

Gabapentin capsules 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 with seizures.

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

What should I tell my healthcare provider before taking gabapentin capsules?

Before taking gabapentin capsules, 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 capsules can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking gabapentin capsules. You and your healthcare provider will decide if you should take gabapentin capsules while you are pregnant.
 - If you become pregnant while taking gabapentin capsules, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of the registry is to collect information about the safety of antiepileptic drugs during pregnancy. You can enroll in this registry by calling 1-888-326-2243.
- are breast-feeding or plan to breast-feed. Gabapentin capsules can pass into breast milk. You and your healthcare provider should decide how you will feed your baby while you take gabapentin capsules.

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

Taking gabapentin capsules 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.

This Medication Guide summarizes the most important information about gabapentin capsules. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about gabapentin capsules that was written for healthcare professionals.

What are the ingredients in gabapentin capsules?

Active ingredient: gabapentin, USP
Inactive ingredients in the capsules: lactose monohydrate, corn starch, and talc.

The 100 mg capsule shell contains gelatin and titanium dioxide. The 300 mg capsule shell contains gelatin, titanium dioxide, and yellow iron oxide.

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

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

Manufactured for:
Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by:
Marksons Pharma Ltd.
Plot No. L-62, L-63, Varma Indl. Estate,
Varma, Goa-403 722, India

Rev. 04/17

100 mg Gabapentin Capsule Package Labels



Manufactured by: 3
Marksans Pharma Ltd, Verna,
Goa-403 722, India

Packaged By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Rev 01/01/19

NDC: 68071-5017-1

Gabapentin 100mg

#100 Capsuels

See manufacturer's label
for full list of ingredients

Product #: R1132100

Rx Only

Gabapentin 100mg
Lot: 000000 NDC: 68071-5017-01
MFR NDC: 49483-605-01 Exp.: 00-00
Serial# 00000000002

Gabapentin 100mg
Lot: 000000 NDC: 68071-5017-01
MFR NDC: 49483-605-01 Exp.: 00-00
Serial# 00000000002

GTIN 00368071501711
Serial# 00000000002
Exp. Date 00-00
LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Take _____ every _____ hours
_____ times a day.

88071501701+100*0000000*000000

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

GABAPENTIN

gabapentin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68071-5017(NDC:49483-605)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GABAPENTIN (UNII: 6CW7F3G59X) (GABAPENTIN - UNII:6CW7F3G59X)	GABAPENTIN	100 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	103

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-5017-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2019	

Marketing Information

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

Labeler - NuCare Pharmaceuticals, Inc. (010632300)**Establishment**

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-5017)

Revised: 6/2024

NuCare Pharmaceuticals, Inc.