

GABAPENTIN- gabapentin capsule
Northwind Pharmaceuticals

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 30, 60 and 90 Capsules.

MedGuide Section

GABAPENTIN- gabapentin capsule

MFG for: TIME CAP LABORATORIES, INC

MEDICATION GUIDE

Gabapentin (gabap) is your Time Cap Laboratories

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?

Do not stop taking gabapentin capsules without first talking to your healthcare provider.

Stopping gabapentin capsules suddenly can cause serious problems.

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 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 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), which could lead to death.
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider should check for other causes.

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 throat or facial swelling. This may cause you to be hospitalized or to stop taking 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[®], Gelusil[®], Gaviscon[®], 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 1-800-272-1222.

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?

Gabapentin capsules may cause serious side effects including:

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
 - viral infections
 - feeling dizzy
 - 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 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 65°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 prescribed. Do not give gabapentin capsules to other people, even if they have the same symptoms that you have. It may harm them.

- 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
- unexplained 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 (neuropathic pain) that follows healing of shingles (a painful rash that occurs 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 on diazepam
- 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 this registry is to collect information about the safety of antiepileptic drugs during pregnancy. You can enroll in this registry by calling 1-888-233-2346.
- 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 alcohol.

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

Rx only

Manufactured for:

Time-Cap Labs, Inc.

7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by:

Markesara Pharma Ltd.

Plot No. L-52, L-53, Verna Indl. Estate,

Verna, Goa-403 722, India

Rev. 04/17

Revised: 9/2019

MFG for: TIME CAP LABORATORIES, INC

300mg Gabapentin Capsule Package Label

NDC: 51655-379-25 LCN#: 1
MFG: 49483-606-50 Rev. 2

Gabapentin 300mg

**60 Capsules
Rx Only**

Lot #: UT51060003

Exp.Date: 01/2020

**Gabapentin 300mg
60 Capsules**
NDC: 51655-379-25
MFG: 49483-606-50
Lot #: UT51060003
Exp.Date: 01/2020

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**Gabapentin 300mg
60 Capsules**
NDC: 51655-379-25
MFG: 49483-606-50
Lot #: UT51060003
Exp.Date: 01/2020

Each capsule contains:
Gabapentin, USP....300MG
Dosage: See prescriber's instructions.
Store between 59 to 86 degrees F.

Store in this tight, light-resistant
container. Protect from moisture.
Keep this out of the reach of
children.

Medication guide is found at
www.fda.gov/drugs/drugsafety/ucm085729

Mfg by: Marksans Pharma Ltd, Verna Indl. Estate,
Verna, Goa-403 722, India
Distributed by: Time-Cap Labs, Inc. 7 Michael
Ave. Farmingdale, NY 11735 Lot# D045E

Repackaged By: Northwind Pharmaceuticals,
Indianapolis, IN 46256



NDC: 51655-379-25

MFG: 49483-606-50

Gabapentin 300mg

60 Capsules

Rx Only

Lot #:

Exp.Date:

Each capsule contains:

Gabapentin, USP....300mg

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NDC: 51655-379-52 LCN#: 1
MFG: 49483-606-50 Rev. 2

Gabapentin 300mg

30 Capsules
Rx Only

Lot #: UT51060004

Exp.Date: 01/2020

Gabapentin 300mg
30 Capsules
NDC: 51655-379-52
MFG: 49483-606-50
Lot #: UT51060004
Exp.Date: 01/2020

Gabapentin 300mg
30 Capsules
NDC: 51655-379-52
MFG: 49483-606-50
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Gabapentin 300mg
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Gabapentin 300mg
30 Capsules
NDC: 51655-379-52
MFG: 49483-606-50
Lot #: UT51060004
Exp.Date: 01/2020

Each capsule contains:
Gabapentin, USP....300MG
Dosage: See prescriber's instructions.
Store between 59 to 86 degrees F.

Store in this tight, light-resistant container. Protect from moisture. Keep this out of the reach of children.

Medication guide is found at
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Indianapolis, IN 46256



NDC: 51655-379-52

MFG: 49483-606-50

Gabapentin 300mg

30 Capsules

Rx Only

Lot #:

Exp.Date:

Each capsule contains:

Gabapentin, USP....300mg

Dosage: See prescriber's instructions.

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Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256

NDC: 51655-379-26 LCN#: 1
MFG: 49483-606-50 Rev. 2

Gabapentin 300mg
90 Capsules
NDC: 51655-379-26
MFG: 49483-606-50
Lot #: UT51060005
Exp.Date: 06/2020

Gabapentin 300mg
90 Capsules
NDC: 51655-379-26
MFG: 49483-606-50
Lot #: UT51060005
Exp.Date: 06/2020

Gabapentin 300mg
90 Capsules
NDC: 51655-379-26
MFG: 49483-606-50
Lot #: UT51060005
Exp.Date: 06/2020

Gabapentin 300mg
90 Capsules
NDC: 51655-379-26
MFG: 49483-606-50
Lot #: UT51060005
Exp.Date: 06/2020



Gabapentin 300mg

90 Capsules Rx Only

Lot #: UT51060005

Exp.Date: 06/2020

Each capsule contains:
Gabapentin, USP....300MG
Dosage: See prescriber's instructions.
Store between 59 to 86 degrees F.

Store in this tight, light-resistant container. Protect from moisture. Keep this out of the reach of children.

Medication guide is found at
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Mfg by: Marksans Pharma Ltd, Verna Indl. Estate, Verna, Goa-403 722, India
Distributed by: Time-Cap Labs, Inc. 7 Michael Ave. Farmingdale, NY 11735 Lot# H085E

Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256

NDC: 51655-379-26

MFG: 49483-606-50

Gabapentin 300mg

90 Capsules

Rx Only

Lot #:

Exp.Date:

Each capsule contains:

Gabapentin, USP....300mg

Dosage: See prescriber's instructions.

Store between 59 to 86 degrees F.

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Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256

GABAPENTIN

gabapentin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51655-379(NDC:49483-606)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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				
Color	yellow	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	104	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-379-25	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/20/2018	
2	NDC:51655-379-52	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2018	
3	NDC:51655-379-26	90 in 1 CAPSULE; Type 0: Not a Combination Product	10/04/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA090007	06/20/2018		

Labeler - Northwind Pharmaceuticals (036986393)

Registrant - Northwind Pharmaceuticals (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals		036986393	relabel(51655-379)