

GABAPENTIN- gabapentin tablet
GABAPENTIN- gabapentin capsule
DIRECT RX

GABAPENTIN

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Gabapentin Tablets USP

(gabapentin)

What is the most important information I should know about gabapentin tablets?

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

Stopping gabapentin tablets suddenly can cause serious problems.

Gabapentin tablets can cause serious side effects including:

1. Suicidal Thoughts. Like other antiepileptic drugs, gabapentin tablets 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?

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- 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 tablets without first talking to a healthcare provider.

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- Stopping gabapentin tablets 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).
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- 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 tablets 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 tablets.

What are gabapentin tablets?

Gabapentin tablets 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 tablets?

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

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

Before taking gabapentin tablets, 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 tablets. You and your healthcare provider will decide if you should take gabapentin tablets while you are pregnant.

- o Pregnancy Registry: If you become pregnant while taking gabapentin tablets, 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 tablets.

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 tablets?

- Take gabapentin tablets exactly as prescribed. Your healthcare provider will tell you how much gabapentin to take.

- o Do not change your dose of gabapentin tablets without talking to your healthcare provider.

- o 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.

- Gabapentin tablets 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 tablets.

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 tablets?

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

What are the possible side effects of gabapentin tablets?

Gabapentin tablets may cause serious side effects including:

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

- problems driving while using gabapentin tablets. See "What I should avoid while taking gabapentin tablets?"

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

- The most common side effects of gabapentin tablets include:

- lack of coordination

- viral infection

- feeling drowsy

- 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 tablets. 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 tablets?

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Store gabapentin tablets at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Keep gabapentin tablets and all medicines out of the reach of children.

General information about the safe and effective use of gabapentin tablets

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

For more information call 1(888)721-7115.

What are the ingredients in gabapentin tablets?

Active ingredient: gabapentin USP

Inactive ingredients corn starch, copovidone, poloxamer 407, magnesium stearate, polyethylene glycol, talc, hypromellose, titanium dioxide, macrogol, polysorbate 80 and purified water.

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

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Manufactured by:

Glenmark Pharmaceuticals Ltd.
India

Manufactured for:

Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430

Questions? 1 (888)721-7115
www.glenmarkpharma.com/usa

December 2017

Manufactured by:
ScieGen Pharmaceuticals, Inc.
Hauppauge, NY 11788 USA

Manufactured for:
Solco Healthcare U.S, LLC
Cranbury, NJ 08512, USA

Rev: 11/17

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

D **GABAPENTIN**
800mg **90 Tabs**

Generic For: **NEURONTIN**
Each tablet contains 800mg of gabapentin USP

Lot# **350-90** Discard After: **12/18**

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

Mfg For: **Glanmark Pharmaceuticals Inc., USA**
Marwah, NJ 07430
NDC 68462-127-05

Mfg Lot: **3/16/2016**

AFQ2T
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
Dosage: See package insert. Store between 68-77 degrees F

M
NDC 61919-350-90

GABAPENTIN 800mg
NDC 61919-350-90 90 Ta
Lot Exp Date 12/18
Mfg NDC 68462-127-05

GABAPENTIN 800mg
NDC 61919-350-90 90 Ta
Lot Exp Date 12/18
Mfg NDC 68462-127-05

GABAPENTIN 800mg
NDC 61919-350-90 90 Ta
Lot Exp Date 12/18
Mfg NDC 68462-127-05

GABAPENTIN 800mg
NDC 61919-350-90 90 Ta
Lot Exp Date 12/18
Mfg NDC 68462-127-05

D **GABAPENTIN**
300mg **60 Caps**

Generic For: **NEURONTIN**
Each capsule contains 300mg of gabapentin, usp

Lot# **417-60** Discard After: **04/19**

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

Mfg For: **Cipla USA, Inc.**
Sunrise, FL 33323
NDC 69097-943-12

Mfg Lot: **1/24/2018**

ANEXC
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
Dosage: See package insert. Store between 68-77 degrees F

M
NDC 61919-417-60

GABAPENTIN 300mg
NDC 61919-417-60 60 Ca
Lot Exp Date 04/19
Mfg NDC 69097-943-12

GABAPENTIN 300mg
NDC 61919-417-60 60 Ca
Lot Exp Date 04/19
Mfg NDC 69097-943-12

GABAPENTIN 300mg
NDC 61919-417-60 60 Ca
Lot Exp Date 04/19
Mfg NDC 69097-943-12

GABAPENTIN 300mg
NDC 61919-417-60 60 Ca
Lot Exp Date 04/19
Mfg NDC 69097-943-12

D **GABAPENTIN**
100mg **90 Caps**

Generic For: **NEURONTIN**
Each capsule contains 100mg of gabapentin, USP

Lot# **661-90** Discard After: **04/20**

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

Dist By: **Solco Healthcare US, LLC**
Cranbury, NJ 08512
NDC 43547-383-50

Mfg Lot: **9/5/2018**

APYKD
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
Dosage: See package insert. Store between 68-77 degrees F

M
NDC 61919-661-90

GABAPENTIN 100mg
NDC 61919-661-90 90 Caps
Lot Exp Date 04/20
Mfg NDC 43547-383-50

GABAPENTIN 100mg
NDC 61919-661-90 90 Caps
Lot Exp Date 04/20
Mfg NDC 43547-383-50

GABAPENTIN 100mg
NDC 61919-661-90 90 Caps
Lot Exp Date 04/20
Mfg NDC 43547-383-50

GABAPENTIN 100mg
NDC 61919-661-90 90 Caps
Lot Exp Date 04/20
Mfg NDC 43547-383-50

GABAPENTIN

gabapentin tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-350(NDC:68462-127)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GABAPENTIN (UNII: 6CW7F3G59X) (GABAPENTIN - UNII:6CW7F3G59X)	GABAPENTIN	800 mg

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (OFF WHITE)	Score	2 pieces
Shape	OVAL	Size	19mm
Flavor		Imprint Code	G;13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-350-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077662	03/16/2016	

GABAPENTIN

gabapentin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-417(NDC:69097-943)
Route of Administration	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
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MANNITOL (UNII: 3OWL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	yellow ((Yellow Opaque Cap and Yellow Opaque Body)	Score	no score
Shape	CAPSULE	Size	23mm
Flavor		Imprint Code	IG322;300mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-417-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090705	12/05/2017	

GABAPENTIN

gabapentin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-661(NDC:43547-383)
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
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

Product Characteristics

Color	white (opaque white colored cap and opaque white colored body)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	SG;179
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-661-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/11/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204989	04/11/2019	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-417, 61919-350, 61919-661)

Revised: 4/2019

DIRECT RX