

**CYCLO/GABA 10/300 PACK- cyclo/gaba 10/300 pack  
TMIG Inc.**

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**Cyclo/Gaba 10/300 Pack**

**4 CONTRAINDICATIONS**

Gabapentin is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

**7 DRUG INTERACTIONS**

- Morphine increases gabapentin concentrations; dose adjustment may be needed ( 5.4, 7.2)

**7.1 Other Antiepileptic Drugs**

Gabapentin is not appreciably metabolized nor does it interfere with the metabolism of commonly coadministered antiepileptic drugs [see *Clinical Pharmacology (12.3)*].

**7.2 Opioids**

Hydrocodone

Coadministration of gabapentin with hydrocodone decreases hydrocodone exposure [see *Clinical Pharmacology (12.3)*]. The potential for alteration in hydrocodone exposure and effect should be considered when gabapentin is started or discontinued in a patient taking hydrocodone.

Morphine

When gabapentin is administered with morphine, patients should be observed for signs of central nervous system (CNS) depression, such as somnolence, sedation and respiratory depression [see *Clinical Pharmacology (12.3)*].

**7.3 Maalox® (aluminum hydroxide, magnesium hydroxide)**

The mean bioavailability of gabapentin was reduced by about 20% with concomitant use of an antacid (Maalox®) containing magnesium and aluminum hydroxides. It is recommended that gabapentin be taken at least 2 hours following Maalox administration [see *Clinical Pharmacology (12.3)*].

**7.4 Drug/Laboratory Test Interactions**

Because false positive readings were reported with the Ames N-Multistix SG® dipstick test for urinary protein when gabapentin was added to other antiepileptic drugs, the more specific sulfosalicylic acid precipitation procedure is recommended to determine the presence of urine protein.

**9 DRUG ABUSE AND DEPENDENCE**

**9.1 Controlled Substance**

Gabapentin is not a scheduled drug.

**9.2 Abuse**

Gabapentin does not exhibit affinity for benzodiazepine, opiate (mu, delta or kappa), or cannabinoid 1 receptor sites. A small number of postmarketing cases report gabapentin misuse and abuse. These individuals were taking higher than recommended doses of gabapentin for unapproved uses. Most of the

individuals described in these reports had a history of poly-substance abuse or used gabapentin to relieve symptoms of withdrawal from other substances. When prescribing gabapentin carefully evaluate patients for a history of drug abuse and observe them for signs and symptoms of gabapentin misuse or abuse (e.g. development of tolerance, self-dose escalation, and drug-seeking behavior).

### **9.3 Dependence**

There are rare postmarketing reports of individuals experiencing withdrawal symptoms shortly after discontinuing higher than recommended doses of gabapentin used to treat illnesses for which the drug is not approved. Such symptoms included agitation, disorientation and confusion after suddenly discontinuing gabapentin that resolved after restarting gabapentin. Most of these individuals had a history of poly-substance abuse or used gabapentin to relieve symptoms of withdrawal from other substances. The dependence and abuse potential of gabapentin has not been evaluated in human studies.

## **10 OVERDOSAGE**

A lethal dose of gabapentin was not identified in mice and rats receiving single oral doses as high as 8000 mg/kg. Signs of acute toxicity in animals included ataxia, labored breathing, ptosis, sedation, hypoactivity, or excitation.

Acute oral overdoses of gabapentin up to 49 grams have been reported. In these cases, double vision, slurred speech, drowsiness, lethargy, and diarrhea were observed. All patients recovered with supportive care. Coma, resolving with dialysis, has been reported in patients with chronic renal failure who were treated with gabapentin.

Gabapentin can be removed by hemodialysis. Although hemodialysis has not been performed in the few overdose cases reported, it may be indicated by the patients clinical state or in patients with significant renal impairment.

If overexposure occurs, call your poison control center at 1-800-222-1222.

## **12 CLINICAL PHARMACOLOGY**

### **12.1 Mechanism of Action**

The precise mechanisms by which gabapentin produces its analgesic and antiepileptic actions are unknown. Gabapentin is structurally related to the neurotransmitter gamma-aminobutyric acid (GABA) but has no effect on GABA binding, uptake, or degradation. *In vitro* studies have shown that gabapentin binds with high-affinity to the  $\alpha 2\delta$  subunit of voltage-activated calcium channels; however, the relationship of this binding to the therapeutic effects of gabapentin is unknown.

## **13 NONCLINICAL TOXICOLOGY**

## **14 CLINICAL STUDIES**

## **16 HOW SUPPLIED/STORAGE AND HANDLING**

Gabapentin capsules USP is supplied as follows:

100 mg capsules:

White hardgelatin capsules imprinted “216” on body with blue ink, available in:

Bottles of 100:NDC 67877-222-01

Bottles of 500:NDC 67877-222-05

Bottles of 1000: NDC 67877-222-10

300 mg capsules:

Yellow hardgelatin capsules imprinted “215” on body with blue ink, available in:

Bottles of 100:NDC 67877-223-01

Bottles of 500:NDC 67877-223-05

Bottles of 1000: NDC 67877-223-10

400 mg capsules:

Orange hardgelatin capsules imprinted “214” on body with blue ink, available in:

Bottles of 100:NDC 67877-224-01

Bottles of 500:NDC 67877-224-05

Bottles of 1000: NDC 67877-224-10

## **Storage**

**Store at 20° to 25°C (68° to 77°F); [see USP Controlled Room Temperature].**

## **17 PATIENT COUNSELING INFORMATION**

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

### Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

Prior to initiation of treatment with gabapentin, instruct patients that a rash or other signs or symptoms of hypersensitivity (such as fever or lymphadenopathy) may herald a serious medical event and that the patient should report any such occurrence to a physician immediately [*see Warnings and Precautions (5.1)*].

### Anaphylaxis and Angioedema

Advise patients to discontinue gabapentin and seek medical care if they develop signs or symptoms of anaphylaxis or angioedema [*see Warnings and Precautions (5.2)*].

### Dizziness and Somnolence and Effects on Driving and Operating Heavy Machinery

Advise patients that gabapentin may cause dizziness, somnolence, and other symptoms and signs of CNS depression. Other drugs with sedative properties may increase these symptoms. Accordingly, although patients' ability to determine their level of impairment can be unreliable, advise them neither to drive a car nor to operate other complex machinery until they have gained sufficient experience on gabapentin to gauge whether or not it affects their mental and/or motor performance adversely. Inform patients that it is not known how long this effect lasts [*see Warnings and Precautions (5.3) and Warnings and Precautions (5.4)*].

## Suicidal Thinking and Behavior

Counsel the patient, their caregivers, and families that AEDs, including gabapentin, may increase the risk of suicidal thoughts and behavior. Advise patients of the need to be alert for the emergence or worsening of symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Instruct patients to report behaviors of concern immediately to healthcare providers [see *Warnings and Precautions (5.6)*].

## Use in Pregnancy

Instruct patients to notify their physician if they become pregnant or intend to become pregnant during therapy, and to notify their physician if they are breast feeding or intend to breast feed during therapy [see *Use in Specific Populations (8.1) and (8.3)*].

Encourage patients to enroll in the NAAED Pregnancy Registry if they become pregnant. This registry is collecting information about the safety of antiepileptic drugs during pregnancy. To enroll, patients can call the toll free number 1-888-233-2334 [see *Use in Specific Populations (8.1)*].

This product's label may have been updated. For full prescribing information, please visit [www.dailymed.nlm.nih.gov](http://www.dailymed.nlm.nih.gov).

Manufactured by:

### **Alkem Laboratories Limited**

ALKEM HOUSE, Lower Parel,

Mumbai – 400 013, INDIA

Distributed by:

Ascend Laboratories, LCC

Montvale, NJ 07645

PT 1702-03

## **Medication Guide**

Gabapentin Capsules USP

**(GA ba PEN tin)**

Read the Medication Guide before you start taking gabapentin 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?**

**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 a 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:

- 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?**

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.
  - o 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.
- o Do not change your dose of gabapentin without talking to your healthcare provider.
- o Take gabapentin capsules with water.

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 between 20° to 25°C (68° to 77°F); [see USP Controlled Room Temperature].

**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.

### **What are the ingredients in gabapentin?**

**Active ingredient:** gabapentin

**Inactive ingredients in the capsules:** anhydrous lactose, cornstarch, and talc. The 100-mg capsule shell also contains: gelatin, sodium lauryl sulfate, and titanium dioxide.

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

The 400-mg capsule shell also contains: gelatin, sodium lauryl sulfate, red iron oxide, titanium dioxide, and yellow iron oxide. The imprinting ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propyl glycol, strong ammonia solution, and titanium dioxide.

### **Manufactured by:**

**Alkem Laboratories Limited**

ALKEM HOUSE, Lower Parel,

Mumbai – 400 013, INDIA

Distributed by:

Ascend Laboratories, LCC.

Montvale, NJ 07645

Revised October 2015

PT 1702-03

Description

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 69176-200-90

**GABAPENTIN CAPSULES, USP**

**300mg**

**PHARMACIST: Dispense the enclosed Medication Guide to each Patient.**

**Rx Only**

**90 Capsules**

## Cyclo/Gaba 10/300 Pack

**Rx only**

NDC 69176-100-02

**Rx only**

NDC 69176-100-02

## Cyclo/Gaba 10/300 Pack

### Pack Contents:

90 - 10mg cyclobenzaprine hydrochloride tablet

90 - 300mg gabapentin capsule

**PHARMACIST:** Dispense all enclosed patient information leaflets to patient.

**WARNING:** keep out of reach of children

Store in cool dry place at 25 C (77 F)

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Store at room  
Temperature (68-77gF)

Dosage and Use: See  
package insert for full  
prescribing information.

Keep out of reach of  
children.

Packaged by: EPM Packaging Inc.  
Lexington, N.E. 68850  
Manufactured by:  
Alkem Laboratories Limited  
Mumbai INDIA  
Distributed by: TMIG Inc. Marietta, GA.  
30062



NDC: 69176-200-90

# Gabapentin Capsules,

## 300 mg

Each Capsule contains 300mg of Gabaper

90 Caps

R<sub>2</sub>

Pharmacist: Dispense the enclosed medica  
guide to each patient

## CYCLOBENZAPRINE TABLETS

10mg

**PHARMACIST: Dispense the enclosed Medication Guide to each Patient.**

Rx Only

90 Capsules

Store at room  
Temperature (68-77gF)

Dosage and Use: See  
package insert for full  
prescribing information.

Keep out of reach of  
children.

Packaged by: EPM Packaging Inc.  
Lexington, N.E. 68850  
Manufactured by:  
Watson Laboratories Inc.  
Corona, Ca 92880, USA  
Distributed by: TMIG Inc. Marietta, GA.  
30062



NDC: 69176-300-90

# Cyclobenzaprine Hydrocl Tablets, USP

## 10 mg

Each Tablet contains 10mg of Cyclobenzaprine Hyd

90 Caps

F

Pharmacist: Dispense the enclosed medica  
guide to each patient

## CYCLO/GABA 10/300 PACK

cyclo/gaba 10/300 pack kit

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69176-100
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69176-100-02	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	07/01/2016	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		1
Part 2		1

## Part 1 of 2

### CYCLOBENZAPRINE HYDROCHLORIDE

cyclobenzaprine hydrochloride tablet, film coated

## Product Information

Item Code (Source)	NDC:69176-300
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYCLOBENZAPRINE HYDROCHLORIDE (UNII: 0VE05JYS2P) (CYCLOBENZAPRINE - UNII:69O5WQ5TI)	CYCLOBENZAPRINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	8 mm
Flavor		Imprint Code	DAN;5658
Contains			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA071611	06/23/2016	

## Part 2 of 2

### GABAPENTIN

gabapentin capsule

#### Product Information

**Item Code (Source)** NDC:69176-200(NDC:67877-223)

**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
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
TALC (UNII: 7SEV7J4R1U)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

#### 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>	215
<b>Contains</b>			

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090858	07/01/2016	

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090858	01/29/2011	

**Labeler** - TMIG Inc. (036572986)

**Registrant** - TMIG Inc (036572986)

**Establishment**

Name	Address	ID/FEI	Business Operations
TMIG Inc.		036572986	repack(69176-100) , manufacture(69176-100)

**Establishment**

Name	Address	ID/FEI	Business Operations
EPM Packaging, Inc		079124340	repack(69176-200)

Revised: 6/2016

TMIG Inc.