Dispense with Medication Guide available at:
documents.amneal.com/mg/carbamazepine-er-tablets.pdf

MEDICATION GUIDE

Carbamazepine (kar″ ba maz′ e peen) Extended-Release Tablets, USP

Read this Medication Guide before you start taking carbamazepine extended-release tablets 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 carbamazepine extended-release tablets?

Do not stop taking carbamazepine extended-release tablets without first talking to your healthcare provider.

Stopping carbamazepine extended-release tablets suddenly can cause serious problems.

Carbamazepine extended-release tablets can cause serious side effects, including:

1. Carbamazepine extended-release tablets may cause rare but serious skin rashes that may lead to death. These serious skin reactions are more likely to happen when you begin taking carbamazepine extended-release tablets within the first four months of treatment but may occur at later times. These reactions can happen in anyone, but are more likely in people of Asian descent. If you are of Asian descent, you may need a genetic blood test before you take carbamazepine extended-release tablets to see if you are at a higher risk for serious skin reactions with this medicine. Symptoms may include:

- skin rash
- hives
- sores in your mouth
- blistering or peeling of the skin

2. Carbamazepine extended-release tablets may cause rare but serious blood problems. Symptoms may include:

- fever, sore throat, or other infections that come and go or do not go away
- easy bruising
- red or purple spots on your body
- bleeding gums or nose bleeds
- severe fatigue or weakness

3. Carbamazepine extended-release tablets may cause allergic reactions or serious problems, which may affect organs and other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions.

Call your healthcare provider right away if you have any of the following:

- swelling of your face, eyes, lips, or tongue
- a skin rash
- painful sores in the mouth or around your eyes
- unusual bruising or bleeding
- frequent infections or infections that do not go away
- fever, swollen glands, or sore throat that do not go away or come and go
- trouble swallowing or breathing
- hives
- yellowing of your skin or eyes
- severe fatigue or weakness
- severe muscle pain

4. Like other antiepileptic drugs, carbamazepine extended-release tablets may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call your 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 carbamazepine extended-release tablets without first talking to a healthcare provider.

Stopping carbamazepine extended-release tablets suddenly can cause serious problems. You should talk to your healthcare provider before stopping.

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.

What are carbamazepine extended-release tablets?

Carbamazepine extended-release tablets are a prescription medicine used to treat:

- certain types of seizures (partial, tonic-clonic, mixed)
- certain types of nerve pain (trigeminal and glossopharyngeal neuralgia)

Carbamazepine extended-release tablets are not a regular pain medicine and should not be used for aches or pains.

Who should not take carbamazepine extended-release tablets?

Do not take carbamazepine extended-release tablets if you:

- have a history of bone marrow depression.
- are allergic to carbamazepine or any of the ingredients in carbamazepine extended-release tablets. See the end of this Medication Guide for a complete list of ingredients in carbamazepine extended-release tablets.
- take nefazodone.
- are allergic to medicines called tricyclic antidepressants (TCAs). Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.
- have taken a medicine called a Monoamine Oxidase Inhibitor (MAOI) in the last 14 days. Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

What should I tell my healthcare provider before taking carbamazepine extended-release tablets?

Before you take carbamazepine extended-release tablets, tell your healthcare provider if you:

- have or have had suicidal thoughts or actions, depression, or mood problems
- have or ever had heart problems
- have or ever had blood problems
- have or ever had liver problems
- have or ever had kidney problems
- have or ever had allergic reactions to medicines
- have or ever had increased pressure in your eye
- have any other medical conditions
- drink grapefruit juice or eat grapefruit
- use birth control. Carbamazepine extended-release tablets may make your birth control less effective. Tell your healthcare provider if your menstrual bleeding changes while you take birth control and carbamazepine extended-release tablets.
- are pregnant or plan to become pregnant. Carbamazepine extended-release tablets may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking carbamazepine extended-release tablets. You and your healthcare provider should decide if you should take carbamazepine extended-release tablets while you are pregnant.

- If you become pregnant while taking carbamazepine extended-release 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 medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334.
- are breastfeeding or plan to breastfeed. Carbamazepine passes into breast milk. You and your healthcare provider should discuss whether you should take carbamazepine extended-release tablets or breastfeed; you should not do both.

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

Taking carbamazepine extended-release tablets with certain other medicines may 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 carbamazepine extended-release tablets?

- Do not stop taking carbamazepine extended-release tablets without first talking to your healthcare provider. Stopping carbamazepine extended-release tablets suddenly can cause serious problems. Stopping seizure medicine suddenly in a patient who has epilepsy may cause seizures that will not stop (status epilepticus).
- Take carbamazepine extended-release tablets exactly as prescribed. Your healthcare provider will tell you how much carbamazepine extended-release tablets to take.
- Your healthcare provider may change your dose. Do not change your dose of carbamazepine extended-release tablets without talking to your healthcare provider.
- Take carbamazepine extended-release tablets with food.
- **Carbamazepine Extended-Release Tablets:**
  - Do not crush, chew, or break carbamazepine extended-release tablets.
  - Tell your healthcare provider if you can not swallow carbamazepine extended-release tablets whole.
- If you take too much carbamazepine extended-release tablets, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking carbamazepine extended-release tablets?

- Do not drink alcohol or take other drugs that make you sleepy or dizzy while taking carbamazepine extended-release tablets until you talk to your healthcare provider. Carbamazepine extended-release tablets taken 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 carbamazepine extended-release tablets affects you. Carbamazepine extended-release tablets may slow your thinking and motor skills.

What are the possible side effects of carbamazepine extended-release tablets?

See **"What is the most important information I should know about carbamazepine extended-release tablets?"**

Carbamazepine extended-release tablets may cause other serious side effects. These include:

- Irregular heartbeat - symptoms include:
  - Fast, slow, or pounding heartbeat
  - Shortness of breath
  - Feeling lightheaded
  - Fainting
- Liver problems - symptoms include:
  - yellowing of your skin or the whites of your eyes
  - dark urine
  - pain on the right side of your stomach area (abdominal pain)
  - easy bruising
  - loss of appetite
  - nausea or vomiting

Get medical help right away if you have any of the symptoms listed above or listed in "What is the most important information I should know about carbamazepine extended-release tablets?"

The most common side effects of carbamazepine extended-release tablets include:

- dizziness
- drowsiness
- problems with walking and coordination (unsteadiness)
- nausea
- vomiting

These are not all the possible side effects of carbamazepine extended-release tablets. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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 carbamazepine extended-release tablets?

- Store **carbamazepine extended-release tablets** at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F).
  - Keep carbamazepine extended-release tablets dry.

Keep carbamazepine extended-release tablets and all medicines out of the reach of children.

General Information about carbamazepine extended-release tablets

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

For more information, go to www.amneal.com or call 1-877-835-5472.

What are the ingredients in carbamazepine extended-release tablets?

Active ingredient: carbamazepine, USP

Inactive ingredients:

Ammonium hydroxide, cellulose acetate, dextrates hydrated, hydroxyethyl cellulose, hydroxypropyl methylcellulose, iron oxide black, magnesium stearate, mannitol, polyethylene glycol, propylene glycol, shellac glaze and sodium lauryl sulfate.

In addition, the 100 mg tablets contain: D&C Yellow #10 Aluminum Lake.

In addition, the 200 mg tablets contain: Red iron oxide.

In addition, the 400 mg tablets contain: D&C Yellow #10 Aluminum Lake and red iron oxide.

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

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