

MEDICATION GUIDE

CARBAMAZEPINE EXTENDED-RELEASE CAPSULES (100 mg, 200 mg and 300 mg)

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

Do not stop taking carbamazepine extended-release capsules without first talking to your healthcare provider. Stopping carbamazepine extended-release capsules suddenly can cause serious problems.

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

1. Carbamazepine extended-release capsules may cause rare but serious rashes that may lead to death. These serious skin reactions are more likely to happen within the first four months of carbamazepine extended-release capsules 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 capsules 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 capsules can also cause other types of allergic reactions or serious problems that may affect organs and other parts of your body such as your liver or blood cells. You may or may not have a rash when you get these types of reactions. Call your healthcare provider right away if you have any of these symptoms:

- frequent fevers or fevers that do not go away
- frequent infections or an infection that does not go away
- unusual bruising or bleeding
- red or purple spots on your body
- severe fatigue or weakness
- unexpected muscle pain that does not go away
- swelling of your face, eyes, lips, or tongue
- swollen glands that do not go away
- yellowing of your skin or the whites of your eyes
- loss of appetite (anorexia) that does not go away
- nausea or vomiting that does not go away

These symptoms may be the first signs of a serious reaction. A healthcare provider should examine you to decide if you should continue taking carbamazepine extended-release capsules.

3. Like other antiepileptic drugs, carbamazepine extended-release capsules 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
- attempt 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 capsules without first talking to a healthcare provider.

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

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 capsules?

Carbamazepine extended-release capsules are a medicine used to treat:

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

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

Who should not take carbamazepine extended-release capsules?

Do not take carbamazepine extended-release capsules if you:

- have a history of bone marrow depression
- are allergic to carbamazepine or any of the ingredients in carbamazepine extended-release capsules. See the end of this Medication Guide for a complete list of ingredients in carbamazepine extended-release capsules.
- take nefazodone
- take delavirdine
- are allergic to antidepressant medications called tricyclic (TCAs).
- have taken a medicine called 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 capsules?

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

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

How should I take carbamazepine extended-release capsules?

- Take carbamazepine extended-release capsules exactly as prescribed. Your doctor will tell you how much carbamazepine extended-release capsules to take.
- Your healthcare provider may change your dose. Do not change your dose of carbamazepine extended-release capsules without talking to your healthcare provider.
- Do not stop taking carbamazepine extended-release capsules without first talking to your healthcare provider. Stopping carbamazepine extended-release capsules suddenly can cause serious problems. Stopping seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).
- Take carbamazepine extended-release capsules with or without food.
- **Do not crush, chew, or break** carbamazepine extended-release capsules or the beads inside of the capsules. But, carbamazepine extended-release capsules can be opened and sprinkled over food such as a teaspoon of applesauce. Tell your healthcare provider if you can not swallow carbamazepine extended-release capsules whole.
- If you take too much carbamazepine extended-release capsules, call your healthcare provider or local Poison Control Center right away.

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

- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking carbamazepine extended-release capsules until you talk to your healthcare provider. Carbamazepine extended-release capsules taken with alcohol or drugs may make your sleepiness or dizziness worse.
- Do not drive, or operate heavy machinery, or do other dangerous activities until you know how carbamazepine extended-release capsules affects you. Carbamazepine extended-release capsules can slow your thinking and motor skills.

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

See “**What is the most important information I should know about carbamazepine extended-release capsules?**”

Carbamazepine extended-release capsules may cause other serious side effects including:

- 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 capsules?**”.

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

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

These are not all the side effects of carbamazepine extended-release capsules. 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 capsules?

- Store carbamazepine extended-release capsules between 59°F to 86°F (15°C to 30°C).
- Keep carbamazepine extended-release capsules out of the light.
- Keep carbamazepine extended-release capsules dry.

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

General information about carbamazepine extended-release capsules

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

For more information, please contact Nostrum Laboratories, Inc. at quality@nostrumpharma.com or 1-877-770-1288.

What are the ingredients in carbamazepine extended-release capsules?

Active ingredient: carbamazepine

Inactive ingredients: silicified microcrystalline cellulose, oleic acid, ethylcellulose, medium chain triglycerides, polyethylene glycols, hypromellose and sodium lauryl sulfate.

In addition:

- the 100 mg capsule shell contains gelatin, D&C Yellow #10, FD&C Blue # 1, FD&C Yellow #6, titanium dioxide and are imprinted with black ink.
- the 200 mg capsule shell contains gelatin, D&C Yellow #10, titanium dioxide and are imprinted with black ink.
- the 300 mg capsule shell contains gelatin, D&C Red #28, FD&C Blue #1, black iron oxide, titanium dioxide and are imprinted with black ink.

The imprinting ink contains the following: black iron oxide, D&C Yellow # 10 Aluminum Lake, FD&C Blue #1/ Brilliant Blue FCF Aluminum Lake, FD&C Blue #2/ Indigo Carmine Aluminum Lake, FD&C Red # 40/ Allura Red AC Aluminum Lake, propylene glycol and shellac glaze.

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

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