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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.
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
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.

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.
take nefazodone.
are allergic to medicines called tricyclic antidepressants (TCAs).
have taken a medicine called a Monoamine Oxidase Inhibitor (MAOI) in the last 14 days.

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.
are pregnant or plan to become pregnant.

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.
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.
Take carbamazepine extended-release tablets with food.

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.
Do not drive, operate heavy machinery, or do other dangerous activities until you know how carbamazepine extended-release tablets affects you.

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°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [See USP Controlled Room Temperature].
Keep carbamazepine extended-release tablets dry.

Keep carbamazepine extended-release tablets and all drugs 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.cadista.com or call 1-800-313-4623.

What are the ingredients in carbamazepine extended-release tablets?

Active ingredient: Carbamazepine

Inactive ingredients: Microcrystalline cellulose, Hypromellose, Ethyl acrylate and Methyl methacrylate copolymer dispersion, Croscarmellose sodium, Talc, Ethyl cellulose aqueous dispersion, Colloidal silicon dioxide, Magnesium stearate and Instacoat universal peach.

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

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Table with 2 main sections: 'UMEDICA LABORATORIES PVT. LTD. SPECIFICATION FOR ARTWORK APPROVAL' and 'CHECKLIST FOR CHECKING ARTWORK & SPECIFICATION'. The first section contains product details like Format No., Product Name, and Specifications. The second section is a grid for checking various attributes like Brand Name, Dosage Form, and QR Code, with a 'Sign with Date' column for approval.