

MEDICATION GUIDE
TEGRETOL[®] and TEGRETOL[®]-XR (Teg-ret-ol)
(carbamazepine)

Tablets, Suspension, Chewable Tablets, Extended-Release Tablets

Read this Medication Guide before you start taking Tegretol or Tegretol –XR (TEGRETOL) 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 TEGRETOL?

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

Stopping TEGRETOL suddenly can cause serious problems.

TEGRETOL can cause serious side effects, including:

- 1. TEGRETOL 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 TEGRETOL 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 TEGRETOL 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. TEGRETOL 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. Like other antiepileptic drugs, TEGRETOL 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 TEGRETOL without first talking to a healthcare provider.

Stopping TEGRETOL 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 is TEGRETOL?

TEGRETOL is a prescription medicine used to treat:

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

TEGRETOL is not a regular pain medicine and should not be used for aches or pains.

Who should not take TEGRETOL?

Do not take TEGRETOL if you:

- have a history of bone marrow depression.
- are allergic to carbamazepine or any of the ingredients in TEGRETOL. See the end of this Medication Guide for a complete list of ingredients in TEGRETOL.
- 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 TEGRETOL?

Before you take TEGRETOL, 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. TEGRETOL may make your birth control less effective. Tell your healthcare provider if your menstrual bleeding changes while you take birth control and TEGRETOL.
- are pregnant or plan to become pregnant. TEGRETOL may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking TEGRETOL. You and your healthcare provider should decide if you should take TEGRETOL while you are pregnant.
 - If you become pregnant while taking TEGRETOL, 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. TEGRETOL passes into breast milk. You and your healthcare provider should discuss whether you should take TEGRETOL 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 TEGRETOL 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 TEGRETOL?

- Do not stop taking TEGRETOL without first talking to your healthcare provider. Stopping TEGRETOL 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 TEGRETOL exactly as prescribed. Your healthcare provider will tell you how much TEGRETOL to take.
- Your healthcare provider may change your dose. Do not change your dose of TEGRETOL without talking to your healthcare provider.

- Take TEGRETOL with food.
- **TEGRETOL-XR tablets:**
 - Do not crush, chew, or break TEGRETOL-XR tablets.
 - Tell your healthcare provider if you can not swallow TEGRETOL-XR whole.
- **TEGRETOL Suspension:**
 - Shake the bottle well each time before use.
 - Do not take TEGRETOL suspension at the same time you take other liquid medicines.
- If you take too much TEGRETOL, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking TEGRETOL?

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

What are the possible side effects of TEGRETOL?

See “**What is the most important information I should know about TEGRETOL?**”

TEGRETOL 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 TEGRETOL”.

The most common side effects of TEGRETOL include:

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

These are not all the possible side effects of TEGRETOL. 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 TEGRETOL?

- Do not store **TEGRETOL Tablets** above 30°C (86°F).
 - Keep TEGRETOL tablets dry.
- Do not store **TEGRETOL Chewable Tablets** above 30°C (86°F).
 - Keep TEGRETOL Chewable Tablets out of the light.
 - Keep TEGRETOL Chewable Tablets tablets dry.
- Store **TEGRETOL-XR tablets** between 15⁰C to 30⁰C (59⁰F to 86⁰F).
 - Keep TEGRETOL XR tablets dry.
- Do not store TEGRETOL Suspension above 30°C (86°F).
 - Shake well before using.
 - Keep TEGRETOL Suspension in a tight, light-resistant container.

Keep TEGRETOL and all medicines out of the reach of children.

General Information about TEGRETOL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TEGRETOL for a condition for which it was not prescribed. Do not give TEGRETOL 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 TEGRETOL. 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 TEGRETOL that is written for health professionals.

For more information, go to www.pharma.us.novartis.com or call 1-888-669-6682.

What are the ingredients in TEGRETOL?

Reference ID: 2912982

Active ingredient: carbamazepine

Inactive ingredients:

- **TEGRETOL tablets:** colloidal silicon dioxide, D&C Red No. 30 Aluminum Lake (chewable tablets only), FD&C Red No. 40 (200-mg tablets only), flavoring (chewable tablets only), gelatin, glycerin, magnesium stearate, sodium starch glycolate (chewable tablets only), starch, stearic acid, and sucrose (chewable tablets only).
- **TEGRETOL Suspension:** Citric acid, FD&C Yellow No. 6, flavoring, polymer, potassium sorbate, propylene glycol, purified water, sorbitol, sucrose, and xanthan gum.
- **TEGRETOL-XR tablets:** cellulose compounds, dextrans, iron oxides, magnesium stearate, mannitol, polyethylene glycol, sodium lauryl sulfate, titanium dioxide (200-mg tablets only).

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