

Medication Guide
EQUETRO (ē-kwě-trō)
(carbamazepine)
Extended-Release Capsules

Read this Medication Guide before you start taking EQUETRO 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 EQUETRO?

Do not stop taking EQUETRO without first talking to your healthcare provider. Stopping EQUETRO suddenly can cause serious problems.

EQUETRO can cause serious side effects, including:

- 1. EQUETRO may cause rare but serious rash that may lead to death. These serious skin reactions are more likely to happen within the first four months of EQUETRO treatment, but may occur at later times. These reactions can happen to 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 EQUETRO to see if you are at higher risk for serious skin reactions with this medicine. If you have any of the problems listed below call your healthcare provider right away:**

- skin rash
- hives
- sores in your mouth
- your skin blisters and peels

- 2. EQUETRO may cause rare but serious blood problems. Symptoms may include:**

- fever, swollen glands, or sore throat that come and go or do not go away
- easy bruising
- red or purple spots on your body
- bleeding gums or nose bleeds

- 3. Like other antiepileptic drugs, EQUETRO may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

Call your healthcare provide 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 or 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 EQUETRO without first talking to a healthcare provider.

Stopping EQUETRO suddenly can cause serious problems. You should talk to your health care 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 EQUETRO?

EQUETRO is a prescription medicine used in adults to treat acute manic and mixed episodes associated with Bipolar Disorder.

It is not known if EQUETRO is safe or effective in children and adolescents.

Who should not take EQUETRO?

Do not take EQUETRO if you:

- have a history of bone marrow depression.
- are allergic to carbamazepine or any of the ingredients in EQUETRO. See the end of this Medication Guide for a complete list of ingredients in EQUETRO.
- are allergic to medicines called tricyclic antidepressants (TCAs) .
- have taken 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.
- are taking nefazodone.

What should I tell my healthcare provider before taking EQUETRO?

Before you take EQUETRO, 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 depression, mood problems, or suicidal thoughts or behavior
- have any other medical conditions
- drink grapefruit juice or eat grapefruit
- use birth control. EQUETRO may make your birth control less effective. Tell your healthcare provider if your menstrual bleeding changes while you take birth control and EQUETRO
- are pregnant or plan to become pregnant. EQUETRO may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking EQUETRO. You and your healthcare provider will decide if you should take EQUETRO while you are pregnant.
 - If you become pregnant while taking EQUETRO, 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. EQUETRO is also an antiepileptic drug. You can enroll in this registry by calling 1-888-233-2334.
- are breastfeeding or plan to breastfeed. EQUETRO can pass into breast milk. You and your healthcare provider should decide if you will take EQUETRO 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 EQUETRO with certain other medicines can cause side effects or affect how well they work. Do not stop or start 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 EQUETRO?

- Take EQUETRO exactly as prescribed. Your healthcare provider will tell you how much EQUETRO to take.

- Your healthcare provider may change your dose. Do not change your dose of EQUETRO without talking to your healthcare provider.
- Do not stop taking EQUETRO without first talking to your healthcare provider. Stopping EQUETRO suddenly can cause serious problems.
- Take EQUETRO with or without food.
- Do not crush, chew, or break EQUETRO capsules or the beads inside the capsules. But, the EQUETRO capsules can be opened and sprinkled over food such as a teaspoon of applesauce.
- Tell your healthcare provider if you can not swallow EQUETRO whole.
- If you take too much EQUETRO, call your healthcare provider or local Poison Control Center right away.

WHAT should I avoid while taking EQUETRO?

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

What are the possible side effects of EQUETRO?

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

EQUETRO may cause other rare, but serious side effects. These include:

- Irregular heart rate – 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.

The most common side effects of EQUETRO include:

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

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

- Store EQUETRO between 59⁰F to 86⁰F (15⁰C to 30⁰C).
- Keep EQUETRO out of the light.
- Keep EQUETRO capsules dry.

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

General Information about EQUETRO

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

For more information, go to www.EQUETRO.com or call 1-866-982-5438.

What are the ingredients in EQUETRO?

Active ingredient: carbamazepine

Inactive ingredients: citric acid, colloidal silicon dioxide, lactose monohydrate, microcrystalline cellulose, polyethylene glycol, povidone, sodium lauryl sulfate, talc, triethyl citrate, and other ingredients.

In addition:

- the 100 mg capsules contain gelatin-NF, FD&C Blue #2, Yellow Iron

- Oxide, and Titanium Dioxide, and are imprinted with white ink
- the 200 mg capsules contain gelatin-NF, Yellow Iron Oxide, FD&C Blue #2, and Titanium Dioxide, and are imprinted with white ink
- the 300 mg capsules contain gelatin-NF, FD&C Blue #2, Yellow Iron Oxide, and Titanium Dioxide, and are imprinted with white ink

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

110705 Issued October 2010

**Validus Pharmaceuticals LLC, 119 Cherry Hill Road, Suite 310,
Parsippany, NJ 07054**

1-866-9VALIDUS (1-866-982-5438)

EQ-043-10
