

## MEDICATION GUIDE

### **Oxcarbazepine (ox'' kar baz' e peen) extended-release tablets, for oral use**

Medication Guide available at <https://www.apotex.com/products/us/mg.asp>

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

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

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

**1. Oxcarbazepine extended-release tablets may cause the level of sodium in your blood to be low.** Symptoms of low blood sodium include:

- nausea
- tiredness, lack of energy
- headache
- confusion
- more frequent or more severe seizures

Similar symptoms that are not related to low sodium may occur from taking oxcarbazepine extended-release tablets. You should tell your healthcare provider if you have any of these side effects and if they bother you or they do not go away.

Some other medicines can also cause low sodium in your blood. Be sure to tell your healthcare provider about all the other medicines that you are taking.

Your healthcare provider may do blood tests to check your sodium levels during your treatment with oxcarbazepine extended-release tablets.

**2. Oxcarbazepine extended-release tablets may also 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
- trouble swallowing or breathing
- a skin rash
- hives
- fever, swollen glands, or sore throat that does not go away or comes and goes
- painful sores in the mouth or around your eyes
- yellowing of your skin or eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- severe muscle pain
- frequent infections that do not go away

Many people who are allergic to carbamazepine are also allergic to oxcarbazepine extended-release tablets. Tell your healthcare provider if you are allergic to carbamazepine.

**3. Like other antiepileptic drugs, oxcarbazepine 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 taking oxcarbazepine extended-release tablets without first talking to a healthcare provider.**

- Stopping oxcarbazepine extended-release tablets suddenly can cause serious problems.
- Stopping a seizure medicine suddenly in a patient who has epilepsy may cause seizures that will not stop (status epilepticus).

Suicidal thoughts or actions may be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

**What is oxcarbazepine extended-release tablets?**

Oxcarbazepine extended-release tablets are a prescription medicine used to treat partial onset seizures in adults and children 6 years of age and older.

Oxcarbazepine extended-release tablets are not for use in children under 6 years of age.

It is not known if oxcarbazepine extended-release tablets are safe and effective in children under 6 years of age.

**Who should not take oxcarbazepine extended-release tablets?**

Do not take oxcarbazepine extended-release tablets if you are allergic to oxcarbazepine or any of the other ingredients in oxcarbazepine extended-release tablets, or to eslicarbazepine acetate. See the end of this Medication Guide for a complete list of ingredients in oxcarbazepine extended-release tablets.

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

**Before taking oxcarbazepine extended-release tablets, tell your healthcare provider about all your medical conditions, including if you:**

- have or have had suicidal thoughts or actions, depression or mood problems.
- have liver problems.
- have kidney problems.
- are allergic to carbamazepine. Many people who are allergic to carbamazepine are also allergic to oxcarbazepine extended-release tablets.

- use birth control medicine. Oxcarbazepine extended-release tablets may cause your birth control medicine to be less effective. Talk to your healthcare provider about the best birth control method to use.
- are pregnant or plan to become pregnant. Oxcarbazepine extended-release tablets may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking oxcarbazepine extended-release tablets. You and your healthcare provider will decide if you should take oxcarbazepine extended-release tablets while you are pregnant.
  - If you become pregnant while taking oxcarbazepine 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. Oxcarbazepine extended-release tablets passes into breast milk. Talk with your healthcare provider about the best way to feed your baby if you take oxcarbazepine extended-release tablets.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking oxcarbazepine 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.

**Especially tell your healthcare provider if you take:** carbamazepine, phenobarbital, phenytoin, or birth control medicine.

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 oxcarbazepine extended-release tablets?**

- Do not stop taking oxcarbazepine extended-release tablets without talking to your healthcare provider. Stopping oxcarbazepine extended-release tablets suddenly can cause serious problems, including seizures that will not stop (status epilepticus).
- Take oxcarbazepine extended-release tablets exactly as prescribed. Your healthcare provider may change your dose. Your healthcare provider will tell you how much oxcarbazepine extended-release tablets to take.
- Take oxcarbazepine extended-release tablets 1 time each day.
- Take oxcarbazepine extended-release tablets on an empty stomach. This means you should take oxcarbazepine extended-release tablets at least 1 hour before or at least 2 hours after a meal.
- Take oxcarbazepine extended-release tablets whole with water or other liquid.
- Do not cut, crush, or chew the tablets before swallowing.
- If you take too much oxcarbazepine extended-release tablets call your healthcare provider right away.

#### **What are the possible side effects of oxcarbazepine extended-release tablets?**

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

**Oxcarbazepine extended-release tablets may cause other serious side effects including:** seizures that can happen more often or become worse, especially in children.

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

- dizziness
- sleepiness
- headache
- balance problems
- tremors
- vomiting
- double vision
- weakness or lack of energy (asthenia)

These are not all the possible side effects of oxcarbazepine 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 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 oxcarbazepine extended-release tablets?**

- Store oxcarbazepine extended-release tablets at room temperature between 68°F to 77°F (20°C and 25°C).
- Keep oxcarbazepine extended-release tablets in a tightly closed container and out of the light.
- Keep oxcarbazepine extended-release tablets dry.

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

**General Information about the safe and effective use of oxcarbazepine extended-release tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use oxcarbazepine extended-release tablets for a condition for which it was not prescribed. Do not give oxcarbazepine extended-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about oxcarbazepine extended-release tablets that is written for health professionals.

**What are the ingredients in oxcarbazepine extended-release tablets?**

**Active ingredient:** oxcarbazepine

**Inactive ingredients:**

**150 mg tablets:** colloidal silicon dioxide, ferric oxide yellow, hydroxypropyl methyl cellulose, magnesium stearate, polyethylene glycol, polyvinyl alcohol, sorbitol, talc.

**300 mg tablets:** colloidal silicon dioxide, ferric oxide red, ferric oxide yellow, hydroxypropyl methyl cellulose, black iron oxide, magnesium stearate, polyethylene glycol, polyvinyl alcohol, sorbitol, talc, titanium dioxide.

**600 mg tablets:** colloidal silicon dioxide, ferric oxide red, hydroxypropyl methyl cellulose, magnesium stearate, polyethylene glycol, polyvinyl alcohol, sorbitol, talc, titanium dioxide.

For more information, go to [www.apotex.com](http://www.apotex.com) or call 1-800-706-5575.

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

**APOTEX INC.**

**OXCARBAZEPINE EXTENDED-RELEASE TABLETS**

**150 mg, 300 mg and 600 mg**

**Manufactured by**

Apotex Inc.  
Toronto, Ontario  
Canada M9L 1T9

**Manufactured for**

Apotex Corp.  
Weston, Florida  
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