

MEDICATION GUIDE
Oxcarbazepine Tablets, USP
(ox kar baz' e peen)
film-coated tablets, for oral use

Oxcarbazepine Tablets, USP contains FD&C yellow no. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C yellow no. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

What is the most important information I should know about oxcarbazepine tablets?

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

Oxcarbazepine tablets can cause serious side effects, including:

1. Oxcarbazepine 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 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 tablets.

2. Oxcarbazepine 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 do not go away or come and go
- frequent infections or infections that do not go away
- 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

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

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

Call a 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
- trouble sleeping (insomnia)
- attempts to commit suicide
- new or worse irritability
- new or worse depression
- acting aggressive, being angry, or violent
- new or worse anxiety
- acting on dangerous impulses

- feeling agitated or restless
- an extreme increase in activity and talking (mania)
- panic attacks
- 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 tablets without first talking to a healthcare provider.

- Stopping oxcarbazepine 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 are oxcarbazepine tablets?

Oxcarbazepine tablets are a prescription medicine used:

- alone or with other medicines to treat partial-onset seizures in adults
- alone to treat partial-onset seizures in children 4 years and older
- with other medicines to treat partial-onset seizures in children 2 years and older

It is not known if oxcarbazepine tablets is safe and effective for use alone to treat partial-onset seizures in children less than 4 years of age **or** for use with other medicines to treat partial-onset seizures in children less than 2 years of age.

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

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

Before taking oxcarbazepine 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 tablets.
- use birth control medicine. Oxcarbazepine 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 tablets may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking oxcarbazepine tablets. You and your healthcare provider will decide if you should take oxcarbazepine tablets while you are pregnant.

If you become pregnant while taking oxcarbazepine 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 passes into breast milk. Talk with your healthcare provider about the best way to feed your baby if you take Oxcarbazepine tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking oxcarbazepine 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 to show your healthcare provider and pharmacist when you get a new medicine.

How should I take Oxcarbazepine tablets?

- Do not stop taking oxcarbazepine tablets without talking to your healthcare provider. Stopping oxcarbazepine tablets suddenly can cause serious problems, including seizures that will not stop (status epilepticus).
- Take oxcarbazepine tablets exactly as prescribed. Your healthcare provider may change your dose. Your healthcare provider will tell you how much oxcarbazepine tablets to take.
- Take oxcarbazepine tablets 2 times a day.
- Take oxcarbazepine tablets with or without food.
- If you take too many oxcarbazepine tablets, call your healthcare provider right away.

What should I avoid while taking Oxcarbazepine tablets?

- Do not drive or operate machinery until you know how oxcarbazepine tablets affects you. Oxcarbazepine tablets may slow your thinking and motor skills.
- Do not drink alcohol or take other drugs that make you sleepy or dizzy while taking oxcarbazepine tablets until you talk to your healthcare provider. Oxcarbazepine tablets taken with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

What are the possible side effects of oxcarbazepine tablets?

See **"What is the most important information I should know about oxcarbazepine tablets?"**

Oxcarbazepine tablets may cause other serious side effects including:

- trouble concentrating
- problems with your speech and language
- feeling confused
- feeling sleepy and tired
- trouble with walking and coordination
- seizures that can happen more often or become worse, especially in children

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 oxcarbazepine tablets?"

The most common side effects of oxcarbazepine tablets include:

- dizziness
- sleepiness
- double vision
- tiredness
- nausea
- vomiting
- problems with vision
- trembling
- problems with walking and coordination (unsteadiness)
- rash

These are not all the possible side effects of oxcarbazepine tablets. 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 oxcarbazepine tablets?

- Store Oxcarbazepine Tablets at 20° - 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F).
- Keep oxcarbazepine tablets dry.

Keep oxcarbazepine tablets and all medicines out of the reach of children.

General Information about the safe and effective use of oxcarbazepine tablets.

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

You can ask your pharmacist or healthcare provider for information about oxcarbazepine tablets that is written for health professionals. For more information, go to www.bpirx.com or call 1-800-367-3395.

What are the ingredients in oxcarbazepine tablets?

Active ingredient: oxcarbazepine

Inactive ingredients:

- **Film-coated tablets:** microcrystalline cellulose, crospovidone, hypromellose, colloidal silicon dioxide, magnesium stearate, talc. Coating: polyvinyl alcohol, talc, titanium dioxide, polyethylene glycol, *FD&C Yellow No. 6 aluminum lake, lecithin, FD&C Blue No. 2 aluminum lake, **FD&C Yellow No. 5 aluminum lake. *Contains FD&C Yellow No. 6 as a color additive. **This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity. Allergen Statement: This product contains soy.

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

Distributed by:
BRECKENRIDGE PHARMACEUTICAL, INC.
Berlin, CT 06037

Manufactured by:
NEXGEN PHARMA, INC.
Irvine, CA 92606

Rev 04/19