



- **Oxcarbazepine**
 - Tablets: 150 mg, 300 mg, 600 mg
 - Oral suspension: 300 mg/5 mL
- **Trileptal®**
 - Tablets: 150 mg, 300 mg, 600 mg
 - Oral Suspension: 300 mg/5 mL
- **Oxtellar XR®**
 - Extended-release tablets: 150 mg, 300 mg, 600 mg

If you or someone you know is in crisis, please call 911 and/or the toll-free National Suicide Prevention Lifeline at 800-273-TALK (8255) to speak with a trained crisis counselor 24/7. A help line and other resources are also available through the National Alliance on Mental Illness at nami.org.



What is oxcarbazepine and what does it treat?

Oxcarbazepine is an antiepileptic medication that works in the brain to prevent and control seizures. It is approved for the treatment of partial seizures.

Oxcarbazepine may also be helpful when prescribed “off-label” for nerve pain or as a mood stabilizer for bipolar disorder. “Off-label” means that it hasn’t been approved by the Food and Drug Administration for this condition. Your mental health provider should justify his or her thinking in recommending an “off-label” treatment. They should be clear about the limits of the research around that medication and if there are any other options.

Bipolar disorder involves episodes of depression and/or mania.

Symptoms of depression include:

- Depressed mood – feeling sad, empty, or tearful
- Feeling worthless, guilty, hopeless, or helpless
- Loss of interest or pleasure in normal activities
- Sleep and eat more or less than usual (for most people it is less)
- Low energy, trouble concentrating, or thoughts of death (suicidal thinking)
- Psychomotor agitation (‘nervous energy’)
- Psychomotor retardation (feeling like you are moving in slow motion)

Symptoms of mania include:

- Feeling irritable or “high”
- Having increased self esteem
- Feeling like you don’t need to sleep
- Feeling the need to continue to talk
- Feeling like your thoughts are too quick (racing thoughts)
- Feeling distracted
- Getting involved in activities that are risky or could have bad consequences (e.g., excessive spending)

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

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

Bipolar disorder requires long-term treatment. Do not stop taking oxcarbazepine, even when you feel better. With input from you, your health care provider will assess how long you will need to take the medicine. Missing doses of oxcarbazepine may increase your risk for a relapse in your mood symptoms.

Do not stop taking oxcarbazepine or change your dose without talking to with your healthcare provider first.

In order for oxcarbazepine to work properly, it should be taken every day as ordered by your healthcare provider.

Periodically, your healthcare provider may ask you to provide a blood sample to make sure the appropriate level of medication is in your body and to assess for side effects, such as changes in blood cell counts and sodium levels.

Are there specific concerns about oxcarbazepine and pregnancy?

If you are planning on becoming pregnant, notify your healthcare provider so that he/she can best manage your medications. People living with bipolar disorder who wish to become pregnant face important decisions. It is important to discuss the risks and benefits of treatment with your doctor and caregivers.

Oxcarbazepine has been associated with an increased risk of craniofacial defects and heart malformations. There may be precautions to decrease the risk of this effect. Do not stop taking oxcarbazepine without first speaking to your healthcare provider. Discontinuing mood stabilizer medications during pregnancy has been associated with a significant increase in symptom relapse.

Regarding breast-feeding, caution is advised since oxcarbazepine does pass into breast milk.

What should I discuss with my healthcare provider before taking oxcarbazepine?

- Symptoms of your condition that bother you the most
- If you have thoughts of suicide or harming yourself
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you experience side effects from your medications, discuss them with your provider. Some side effects may pass with time, but others may require changes in the medication.
- Any other psychiatric or medical problems you have
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies you have
- Other non-medication treatment you are receiving, such as talk therapy or substance abuse treatment. Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you drink alcohol or use illegal drugs

How should I take oxcarbazepine?

Oxcarbazepine is usually taken once or twice a day with or without food.

Typically patients begin at a low dose of medicine and the dose is increased slowly over several weeks.

The dose usually ranges from 900-1200 mg per day. People taking this medication for seizure control may take up to 2400 mg daily. Only your healthcare provider can determine the correct dose for you.

Oxcarbazepine suspension: Measure your dose with a dosing spoon or oral syringe, which you can get from your pharmacy. Before using, shake the bottle well to ensure the medicine is mixed thoroughly. Your dose can be mixed in a small glass of water just prior to taking or may be swallowed directly from the dosing spoon.

Use a calendar, pillbox, alarm clock, or cell phone alert to help you remember to take your medication. You may also ask a family member a friend to remind you or check in with you to be sure you are taking your medication.

What happens if I miss a dose of oxcarbazepine?

If you miss a dose of oxcarbazepine, take it as soon as you remember, unless it is closer to the time of your next dose. Discuss this with your healthcare provider. Do not double your dose or take more than what is prescribed.

What should I avoid while taking oxcarbazepine?

Avoid drinking alcohol or using illegal drugs while you are taking oxcarbazepine. They may decrease the benefits (e.g., worsen your condition) and increase adverse effects (e.g., sedation, dizziness) of the medication.

What happens if I overdose with oxcarbazepine?

If an overdose occurs call your doctor or 911. You may need urgent medical care. You may also contact the poison control center at 1-800-222-1222.

A specific treatment to reverse the effects of oxcarbazepine does not exist.

What are the possible side effects of oxcarbazepine?

Common side effects

- Dizziness
- Drowsiness
- Vision changes
- Nausea/vomiting
- Headache
- Fatigue
- Uncoordinated movements
- Tremor

Rare/Serious side effects

Oxcarbazepine can cause a decrease in the body's sodium level. Some signs of low sodium include nausea, tiredness, lack of energy, headache, confusion, or more frequent or more severe seizures.

Oxcarbazepine 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.

In rare cases (<1%) a severe, spreading rash with blistering of the skin in patches over the entire body along with fever, headache and cough can occur (Stevens-Johnson syndrome). Although this is rare with oxcarbazepine, discontinuation of this medication is necessary. Rare cases of severe allergic reactions have been reported. Symptoms include swelling of the face, eyes, lips, or tongue, difficulty swallowing or breathing. If you experience any of these side effects, it is important to seek medical care immediately.

Studies have found that individuals who take antiepileptic medications including oxcarbazepine may be twice as likely to have suicidal thoughts or behaviors as individuals who take placebo (inactive medication). These thoughts or behaviors are rare and occurred in approximately 1 in 500 patients taking the antiepileptic class of medications. If you experience any thoughts or impulses to hurt yourself, you should contact your doctor immediately.

Are there any risks for taking oxcarbazepine for long periods of time?

To date, there are no known problems associated with long term use of oxcarbazepine. It is a safe and effective medication when used as directed.

It is important to note that some of the side effects listed above (particularly changes in blood sodium, rash, and suicidal thoughts) may continue to occur or worsen if you continue taking the medication. It is important to follow up with your doctor for blood work and to contact your doctor immediately if you notice any skin rash or changes in mood or behavior.

What other medications may interact with oxcarbazepine?

The seizure medications phenobarbital and phenytoin may **decrease** the effects of oxcarbazepine

Oxcarbazepine may **increase** the effects of phenobarbital and phenytoin

Oxcarbazepine may **decrease** the level and effects of:

- Oral contraceptives
- Anti-rejection medications used in organ transplants, like tacrolimus (Prograf®) and cyclosporine (Neoral®, Sandimmune®)
- Certain blood pressure medications, such as amlodipine (Norvasc®) or felodipine (Plendil®)

How long does it take for oxcarbazepine to work?

It is very important to tell your doctor how you feel things are going during the first few weeks after you start taking oxcarbazepine and whether or not you are experiencing any side effects from the medication. It will probably take several weeks to see big enough changes in your symptoms to decide if oxcarbazepine is the right medication for you.

Mood stabilizer treatment is generally needed lifelong for persons with bipolar disorder. Your doctor can best discuss the duration of treatment you need based on your symptoms and illness.

Summary of Black Box Warnings

Currently there are no FDA Black Box warnings for oxcarbazepine

Important Disclosure: This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.