

MEDICATION GUIDE
OXCARBAZEPINE ORAL SUSPENSION
 (ox car baz' e peen)

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

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

Oxcarbazepine oral suspension can cause serious side effects, including:

- Oxcarbazepine oral suspension 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 oral suspension. 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 oral suspension.

- Oxcarbazepine oral suspension 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
- 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 or infections that do not go away

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

- Like other antiepileptic drugs (AEDs), Oxcarbazepine oral suspension 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
- 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 oral suspension without first talking to a healthcare provider.

- Stopping oxcarbazepine oral suspension 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 oral suspension?

Oxcarbazepine oral suspension is 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 oral suspension 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 oral suspension if you are allergic to oxcarbazepine oral suspension or any of the other ingredients in oxcarbazepine oral suspension, or to eslicarbazepine acetate. See the end of this Medication Guide for a complete list of ingredients in oxcarbazepine oral suspension.

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

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

If you become pregnant while taking oxcarbazepine oral suspension, talk to your healthcare provider about registering with the North American

Oxcarbazepine oral suspension, USP
Oral Suspension 300 mg/5 mL

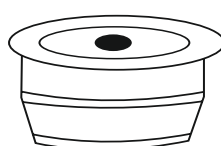
Each 5 mL contains 300 mg oxcarbazepine

Instructions for Use

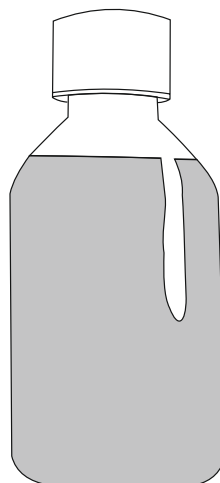
Read these instructions carefully to learn how to use the medicine dispensing system correctly.

The Medicine Dispensing System

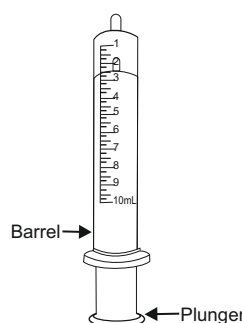
There are 3 parts to the dispensing system:



1. A **plastic adapter** that you push into the neck of the bottle the first time that you open the bottle. The adapter must always stay in the bottle.



2. A **bottle** containing 250 mL of the medicine, with a child-resistant cap. Always replace the cap after use.



3. A 10 mL **oral dosing syringe** that fits into the plastic adapter to withdraw the prescribed dose of medicine from the bottle.

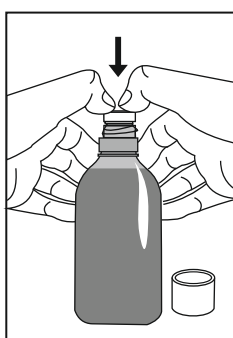
Preparing the Bottle



1. Shake the bottle of medicine for **at least 10 seconds**.

2. Remove the child-resistant cap by pushing it **firmly** down and turning it counterclockwise – to the left (as shown on the top of the cap).

Note: Save the cap so you can close the bottle after each use.



3. Hold the open bottle upright on a table and push the plastic adapter **firmly** into the neck of the bottle as far as you can.

4. **Replace the cap to be sure that the adapter has been fully forced into the neck of the bottle.**

Note: You may not be able to push the adapter fully down, but it will be forced into the bottle when you screw the cap back on.

Now the bottle is ready to use with the syringe. The adapter must always stay in the bottle. The child-resistant cap should seal the bottle in between use.

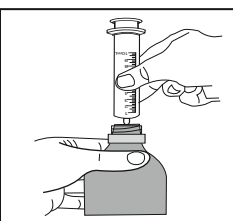
Taking the Medicine



1. Shake the bottle well. Prepare the dose right away.

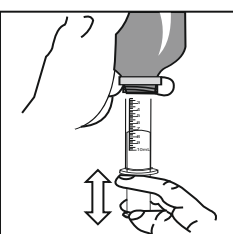
2. Push and turn the child-resistant cap to open the bottle.

Note: Always replace the cap after use.



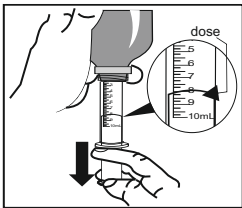
3. Check that the plunger is all the way down inside the barrel of the syringe.

4. Keep the bottle upright and push the syringe **firmly** into the plastic adapter.



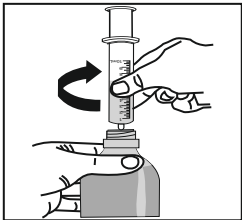
5. Hold the syringe in place and carefully turn the bottle upside down.

6. Slowly pull the plunger out so that the syringe fills with some medicine. Push the plunger back in just far enough to completely push out any large air bubbles that may be trapped in the syringe.

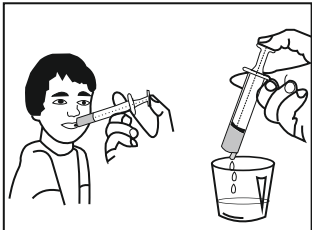


7. Slowly pull the plunger out until the top edge of the plunger is exactly level with the marker on the syringe barrel for the prescribed dose.

Note: If the prescribed dose is more than 10 mL, you will need to refill the syringe to make up the full dose.



8. Carefully turn the bottle upright. Take out the syringe by gently twisting it out of the plastic adapter. The plastic adapter should stay in the bottle.



9. You can mix the dose of medicine in a small glass of water before it is swallowed, or you can drink it directly from the syringe.

a. **If you mix the medicine with water**, add some water to a glass. Push in the plunger on the syringe all the way to empty all the medicine into the glass. Stir the medicine in the water and drink it all.

b. **If you use the syringe to take the medicine**, the patient must sit upright. Push the plunger **slowly** to let the patient swallow the medicine.

10. Replace the child-resistant cap after use.

Cleaning: After use, rinse the syringe with warm water and allow it to dry thoroughly.

MACLEODS

Manufactured for:

Macleods Pharma USA, Inc.
Princeton, NJ 08540

Manufactured by:

Macleods Pharmaceutical Ltd.
Baddi, Himachal Pradesh-174101 India

Revised: August 2025

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 oral suspension passes into breast milk. Talk with your healthcare provider about the best way to feed your baby if you take oxcarbazepine oral suspension.

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

- Do not stop taking oxcarbazepine oral suspension without talking to your healthcare provider. Stopping oxcarbazepine oral suspension suddenly can cause serious problems, including seizures that will not stop (status epilepticus).
- Take oxcarbazepine oral suspension exactly as prescribed. Your healthcare provider may change your dose. Your healthcare provider will tell you how much oxcarbazepine oral suspension to take.
- Take oxcarbazepine oral suspension 2 times a day.
- Take oxcarbazepine oral suspension with or without food.
- Before taking oxcarbazepine oral suspension shake the bottle well and use the oral dosing syringe that comes with your oral suspension to measure the amount of medicine needed. Oxcarbazepine oral suspension can be mixed in a small glass of water, or swallowed directly from the syringe. Clean the syringe with warm water and let it dry after each use.
- If you take too much oxcarbazepine oral suspension, call your healthcare provider right away.

What should I avoid while taking oxcarbazepine oral suspension?

- Do not drive or operate machinery until you know how oxcarbazepine oral suspension affects you. Oxcarbazepine oral suspension may slow your thinking and motor skills.
- Do not drink alcohol or take other drugs that make you sleepy or dizzy while taking Oxcarbazepine oral suspension until you talk to your healthcare provider. Oxcarbazepine oral suspension 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 oral suspension?

See **“What is the most important information I should know about oxcarbazepine oral suspension?”**

Oxcarbazepine oral suspension 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 oral suspension?”

The most common side effects of oxcarbazepine oral suspension 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 oral suspension. 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 oral suspension?

- Keep oxcarbazepine oral suspension in the original container and use within 7 weeks of first opening the bottle. Shake well before using.

Keep oxcarbazepine oral suspension and all medicines out of the reach of children.

General Information about the safe and effective use of oxcarbazepine oral suspension.

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

What are the ingredients in oxcarbazepine oral suspension?

Active ingredient: oxcarbazepine

Inactive ingredients:

- **Oral suspension:** carboxymethylcellulose sodium, noncrystallizing sorbitol solution, microcrystalline cellulose and carboxymethylcellulose sodium, ascorbic acid, methyl paraben, propyl paraben, sorbic acid, propylene glycol, saccharin sodium, colloidal silicon dioxide, flavour plum, sodium hydroxide, hydrochloric acid, purified water.

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

Revised: August 2025