



# Trileptal (oxcarbazepine)

Generic name: Oxcarbazepine

Available strengths: 150 mg, 300 mg, 600 mg tablets;  
300 mg/5 mL oral suspension

Available in generic: No

Drug class: Anticonvulsant/mood stabilizer

## General Information

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**Trileptal (oxcarbazepine)** is better known as an anticonvulsant—a medication for treating epilepsy. This may present some confusion for patients, as well as their families, when they are prescribed an anticonvulsant without a history of seizures. In the past decade, anticonvulsants have increasingly become the medications of choice for the treatment of bipolar disorder, particularly in acute mania. Trileptal was approved by the U.S. Food and Drug Administration only for the treatment of seizures. The use of a medication for its approved indication is called *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* (“off-label”) uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of those treatments. Unlabeled uses for Trileptal include treatment of bipolar disorder, panic disorder, and agitation. When Trileptal and other anticonvulsants are used for treating mood disorders, they are considered **mood stabilizers**.

Trileptal’s chemical structure is very similar to that of Tegretol (carbamazepine), another anticonvulsant commonly used as a mood stabilizer. Trileptal, however, is better tolerated and has fewer significant drug interactions than Tegretol. Although Trileptal was introduced only recently in the United States, it has been used to treat bipolar disorder in Europe for many years. In limited clinical studies, it was shown to be effective in managing acute mania. Trileptal’s effectiveness in preventing relapse in bipolar disorder remains equivocal, for it has not been demonstrated thus far. Because it is structurally similar to Tegretol, which is an effective mood stabilizer in maintenance therapy, Trileptal is expected to offer similar treatment benefits.

It is not totally clear how some anticonvulsants are effective for seizures and bipolar disorder. The anticonvulsants, which have very complex effects on the central nervous system, may be effective by controlling “kindling” in the areas of the brain from which the psychiatric disorder emanates. Kindling is a phenomenon that occurs when repeated subthreshold stimulation is applied to certain regions of the brain and sensitizes them, setting off a cascade of events leading to seizures or manic behavior. By decreasing electrical conduction or neurotransmitter activity in unstable brain cells, anticonvulsants are effective in controlling seizures and bipolar illness.

Trileptal is not associated with any significant risk of **agranulocytosis** and **aplastic anemia**, which are potentially fatal conditions associated with Tegretol. Agranulocytosis is a condition in which the level of a particular type of white blood cells (**granulocytes**) is dramatically and dangerously low. Aplastic anemia is a condition in which the bone marrow stops producing blood cells, including platelets (important for clotting), white blood cells, and red blood cells. Because Trileptal has an improved safety profile and fewer drug interactions than Tegretol, physicians generally prefer to use it over the older anticonvulsant. The disadvantage of Trileptal, however, is cost; unlike Tegretol, Trileptal is not available in a generic form.

## Dosing Information

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The starting dosage of Trileptal is usually 300 mg twice a day. The dosage is then increased gradually, by approximately 300 mg every 3 days, to 2,400 mg/day in a twice-daily regimen. Seniors and individuals with renal impairment may require lower dosages.

## Common Side Effects

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The most common side effects from Trileptal are somnolence, tiredness, dizziness, and gastrointestinal symptoms, including nausea, vomiting, constipation, and abdominal pain. When starting Trileptal, patients may experience mental sluggishness and difficulty in concentration and may feel tired and sleepy. Other common side effects, usually at higher dosages, include problems with double vision (**diplopia**), jerky eye movements (**nystagmus**), and impaired coordination or clumsiness when walking (**ataxia**). These side effects are generally temporary and subside as tolerance to the medication develops, but if they persist, the dosage may be lowered to make it more tolerable.

## Adverse Reactions and Precautions

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Trileptal may cause drowsiness and impair alertness, especially at the start of therapy. Patients should use caution when driving or performing tasks that require alertness.

In patients with significant renal impairment, the dosage of Trileptal should be reduced to prevent toxic levels. The active metabolite of Trileptal is excreted primarily by the kidneys, and in the presence of renal impairment, the medication may accumulate significantly in the body and result in a toxic reaction.

Trileptal may induce some bothersome central nervous system effects such as disturbance of cognition, difficulty with concentration, impaired coordination, and clumsiness in walking. The risks of falling and accidents may be especially hazardous for seniors.

Trileptal may lower serum sodium levels (**hyponatremia**), and symptoms of hyponatremia may develop if the sodium level is not normalized. The body's sodium concentration is regulated by the mechanisms of thirst, hormones (e.g., antidiuretic hormone), and the kidneys. Disturbance of sodium balance can disrupt many of the body's physiological functions, with serious clinical consequences. Usually, Trileptal-induced hyponatremia is mild and produces no symptoms (asymptomatic), but in clinically significant hyponatremia, symptoms may include loss of appetite, nausea and vomiting, confusion, lethargy, headache, and agitation. Individuals who are also receiving medications known to decrease serum sodium levels (e.g., thiazide diuretics) or those with a medical condition that disrupts sodium balance may be particularly susceptible to hyponatremia during treatment with Trileptal. The serum sodium levels of patients who are taking Trileptal should be monitored routinely, especially during the first 3 months of treatment, when hyponatremia generally occurs.

## Use in Pregnancy and Breastfeeding: Pregnancy Category C

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There are no adequate clinical studies of Trileptal in pregnant women to determine the medication's risk to the woman and fetus. However, because Trileptal is structurally similar to Tegretol, which is known to cause birth defects, it may carry similar risk and should not be used during pregnancy. Trileptal and its metabolite can cross the placenta and cause harmful effects to the fetus. The use of Trileptal should therefore be avoided in pregnancy whenever possible, especially in the first trimester. However, if Trileptal is stopped and mania reoccurs, the physician may discuss the need to restart Trileptal after the first trimester or seek an alternative medication or treatment.

Nursing mothers should not take Trileptal, because it is excreted in breast milk and may be harmful to the baby when ingested. If stopping the medication is not an alternative, breastfeeding should not be started or should be discontinued.

## Possible Drug Interactions

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Trileptal can affect the liver enzymes that metabolize other medications, lowering their blood levels and diminishing their effectiveness. Conversely, other medications can affect the metabolism of Trileptal and decrease its blood levels. The clinically significant drug interactions reported with Trileptal are summarized in the table below.

Oral contraceptives containing ethinyl estradiol and levonorgestrel (e.g., Demulen, Nordette, Alesse)	When Trileptal is taken in combination with oral contraceptives that contain ethinyl estradiol and levonorgestrel, it can decrease the levels of these hormones and their effectiveness, which may result in unintended pregnancy.
Tegretol, Calan (verapamil), and Depakote	Any of these medications, when taken in combination with Trileptal, can lower the blood levels of Trileptal and decrease its effectiveness.
Dilantin and phenobarbital	Trileptal may inhibit the metabolism of these medications and increase their blood levels, which may potentially result in toxicity. Conversely, these medications can lower the blood levels of Trileptal and decrease its effectiveness.
Plendil (felodipine)	Blood levels of Plendil, a calcium channel blocker, may be decreased by Trileptal, decreasing its effectiveness.

Patients taking Trileptal should not consume alcohol because the combination may increase sedation and drowsiness. Moreover, the sedative effects of alcohol may act as a depressant, obscuring the therapeutic effects of Trileptal and complicating treatment.

## Overdose

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In the reported cases of Trileptal overdose, all of the patients recovered with supportive treatment. The extent of peril from overdose depends on the amount ingested and the size and age of the person. In small children,

for example, the lethal dosage may be much lower than for an average adult. Symptoms of Trileptal toxicity include neuromuscular disturbances such as nystagmus, muscle jerks (**myoclonus**), increased reflex reactions (**hyperreflexia**), and severe nausea and vomiting. Higher overdose may lead to respiratory depression, convulsions, cardiac arrhythmia, shock, coma, and death.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency department for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

## Special Considerations

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- If you miss a dose, take it as soon as possible, within 2–3 hours of the scheduled dosing. If it is close to your next scheduled dose, skip the missed dose and continue on your regular dosing schedule, but do not take double doses.
- Take Trileptal immediately after meals or with food to decrease stomach upset.
- Contact your physician if you have excessive thirst, lethargy, headaches, nausea and vomiting, difficulty in concentrating, or confusion. These may be signs and symptoms of hyponatremia.
- Trileptal may cause sedation and drowsiness, especially during initiation of therapy, and impair your alertness. Use caution when driving or performing tasks that require alertness.
- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of your medication.
- Keep your medication out of reach of children. Overdose in small children is very dangerous.

*If you have any questions about your medication, consult your physician or pharmacist.*

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