

## Trileptal (Oxcarbazepine)

### Brand and Generic Names:

- Trileptal®

Tablets: 150mg, 300mg, 600mg

Liquid Suspension: 300mg/5mL

- Generic name: oxcarbazepine

### What is Trileptal® and what does it treat?

Oxcarbazepine is an anticonvulsant medication that is most commonly used to treat seizures in patients with epilepsy. Although epilepsy is the only FDA approved indication, oxcarbazepine is also used, and has been studied for treatment of bipolar disorder

A depressive episode or depression occurs when a person experiences several of the following symptoms at the same time: "low" or depressed mood (for example, sad, empty, tearful); decreased interest in most or all activities; changes in appetite (usually decreased); changes in sleep (usually poor sleep); loss of energy; feeling worthless/guilty/hopeless/helpless; psychomotor agitation or retardation (i.e. thoughts/movements speeding up or slowing down); difficulty concentrating, and thoughts of death (suicidal thinking).

A manic episode, or mania, is when a person experiences several of the following symptoms at the same time: "high" or irritable mood, very high self esteem, decreased need for sleep, pressure to keep talking, racing thoughts, being easily distracted, frequently involved in activities with large risk for bad consequences (for example, excessive buying sprees).

Bipolar disorder is a brain disorder (mental illness) that exposes people to these mood changes over the course of time. Bipolar disorder affects more than two million American

each year, but patients with this disorder can lead fulfilling lives when they receive proper treatment. Unfortunately, many people with this illness do not receive treatment.

### **What is the most important information I should know about Trileptal®?**

- Bipolar disorder requires long-term treatment. Only your healthcare provider can determine the length of oxcarbazepine treatment that is right for you. Missing doses of oxcarbazepine may increase your risk for a relapse in your mood symptoms. It may also increase the risk of troublesome side effects such as seizures.
- Do not stop taking oxcarbazepine or change your dose without talking with your healthcare provider first.
- Tell your healthcare provider if you are taking birth control pills. Oxcarbazepine may reduce the effectiveness of these medications, putting you at risk for pregnancy. The dose of your birth control pills may need to be adjusted, or you may need to use an additional method of birth control while taking oxcarbazepine.
- Oxcarbazepine may reduce the effectiveness of some medications. Make sure your healthcare provider knows what other medications you are taking.
- Oxcarbazepine may make you drowsy. Do not drive or operate machinery until you know how this medication affects you.
- You should not drink alcohol or use illegal drugs while taking oxcarbazepine.
- In order for oxcarbazepine to work properly, it should be taken every day as ordered by your healthcare provider.

### **Are there specific concerns about Trileptal® 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 illness who wish to become pregnant face important decisions about the risks and benefits of the medications as they relate to the illness and to the fetus. This is a complex decision as untreated bipolar disorder has risks to the fetus as well as the mother. There are many dimensions to these choices, so be sure to discuss with your doctor and caregivers.

Since oxcarbazepine is a newer medication, there is less information about its use in pregnant women. Oxcarbazepine has caused birth defects in animals, but there are no human studies. However, other similar anticonvulsants have been shown to cause birth defects in humans.

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

### **What should I discuss with my healthcare provider before taking Trileptal®?**

Tell your doctor if you have taken oxcarbazepine before. If you are allergic to oxcarbazepine, tell your doctor and pharmacist exactly what it did to you before taking even one dose. If you have had an allergic reaction to carbamazepine (Tegretol®) in the

past, you should also inform your healthcare provider, since you are more likely to have an allergic reaction to oxcarbazepine. In addition, you should discuss the following:

- Symptoms that are most bothersome to you about your condition
- If you have thoughts of suicide
- Any medical problems you have, especially kidney disease and thyroid disease
- Medications you have taken in the past to treat bipolar disorder, whether they were effective or caused any adverse effects

All other medications you are currently taking and any medication allergies you have.

- Any medication side effects that you may have experienced in the past, or are currently experiencing
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you smoke, drink alcohol, or use illegal drugs

### **How should I take Trileptal®?**

- Oxcarbazepine is usually taken two times a day, with or without food. Your healthcare provider will determine the dose that is right for you based upon your response.
- Use a pillbox or calendar to help you remember to take your medication.

### **What happens if I miss a dose of Trileptal®?**

If you miss a dose of oxcarbazepine, take it as soon as you remember if it is not too close to when your next dose is due. If it is close to your next dose, wait until then to take the medication and skip the missed dose. Do not double your next dose or take more than your prescribed dose.

### **What should I avoid while taking Trileptal®?**

- Oxcarbazepine may cause dizziness or drowsiness, especially when first starting the medication. Make sure you know how you react to the medication before you drive, operate machinery, or do other activities that may be dangerous if you are not alert.
- Avoid drinking alcohol or using illegal drugs while you are taking mood stabilizing medications because the beneficial effects of the medication may be decreased and adverse effects may be increased (e.g. sedation).

### **What happens if I overdose with Trileptal®?**

If an overdose occurs, whether intentional or accidental, immediate medical attention is necessary. Call your doctor or emergency medical service (911). You may also contact the poison control center (1-800-222-1222).

Symptoms that may occur in an overdose include: decreased heart rate, low blood pressure, dizziness, and sedation. An overdose of oxcarbazepine can cause low sodium blood levels, potentially leading to seizures and coma.

A specific antidote for oxcarbazepine does not exist.

### **What are the possible side effects of Trileptal®?**

Potential side effects of oxcarbazepine include: headache, dizziness, sedation, unsteady or abnormal gait, fatigue, tremor, double vision, abnormal vision, nausea, vomiting, stomach pain, and indigestion.

Memory impairment, concentration difficulties, rash, and weight gain have also been reported.

Oxcarbazepine can cause a decrease in the body's sodium level, especially at higher doses. Although low sodium levels may not cause observable symptoms, some signs of low sodium include nausea, drowsiness, impaired consciousness, or confusion.

Stevens-Johnson Syndrome, a serious skin reaction, has occurred with oxcarbazepine in rare cases. Rare cases of severe allergic reactions have been reported. Symptoms included swelling of the face, eyes, lips, or tongue, difficulty swallowing or breathing.

Talk with your healthcare provider if you experience side effects that are bothersome to you.

Contact your healthcare provider immediately if you develop a skin reaction, fever, swelling, or shortness of breath.

### **Are there any risks for taking Trileptal® for long periods of time?**

To date, there are no known problems associated with long term use of oxcarbazepine. However, if anything new or unusual happens that you think might be due to medications you are taking, talk with your healthcare provider as soon as possible.

### **What other drugs may interact with Trileptal®?**

Oxcarbazepine may decrease the effectiveness of several other medications by increasing their breakdown and elimination from the body. Similarly, the effectiveness of oxcarbazepine may be reduced by other anticonvulsants. People who are taking oxcarbazepine should consult their doctor before taking or discontinuing the following:

- Oral contraceptives (birth control pills)
- Anticonvulsants
  - Dilantin® (phenytoin)
  - Depakote® (valproic acid)

- Tegretol<sup>®</sup> (carbamazepine)
- Luminal<sup>®</sup> (phenobarbital)
- Lamictal<sup>®</sup> (lamotrigine)
- Calcium Channel Blockers
  - Calan<sup>®</sup>, Covera-HS<sup>®</sup>, Isoptin SR<sup>®</sup> (verapamil)
  - Plendil<sup>®</sup> (felodipine)
- Antibiotics
  - Biaxin<sup>®</sup> (clarithromycin)
  - Ketek<sup>®</sup> (telithromycin)
- Anticholesterol Agents like Zocor<sup>®</sup> (simvastatin)

Oxcarbazepine may also increase the levels of several other medications by decreasing their breakdown and elimination from the body. This may put people at risk for side effects. People who are taking oxcarbazepine should consult their doctor before taking or discontinuing any medications.

### **How long does it take for Trileptal<sup>®</sup> to work?**

Several weeks are often required for oxcarbazepine to reach its maximum effectiveness; however, improvement in some symptoms may occur sooner.

It is very important to tell your doctor how you feel things are going during the first few weeks after you start taking oxcarbazepine. It will probably take several weeks to see enough changes in your symptoms to decide if oxcarbazepine is helpful for you.

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

*Updated by Leena B. Menon, Pharm.D.  
(June 2007)*



*NAMI wishes to thank the College of Psychiatric and Neurological Pharmacists for producing this fact sheet.*

**For further information please contact the pharmaceutical company listed below.**

Novartis	Patient Assistance Program PO Box 66556 St. Louis, MO 63166	800-277-2254	<a href="http://www.novartis.com">www.novartis.com</a>
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