

Patient Name: _____ Date: _____

Doctor Name: _____ Emergency Phone Number: _____

Pharmacy: _____ Number: _____

What is Oxcarbazepine?

Oxcarbazepine (also known under the brand name of Trileptal) is a medicine that has been approved by the Food and Drug Administration to treat complex partial and generalized tonic clonic (grand mal) seizures. This medicine is not helpful against myoclonic or absence seizures. It can be used alone or with other seizure medicines in adults and children four years of age and older.

- Sometimes medicines are used to treat other conditions, so be sure to ask your doctor why you are taking this medicine.
- Oxcarbazepine is not available in generic form in the United States, but generic versions are available in some other countries.
- The dose of oxcarbazepine and how it is taken may vary depending on why it is being given, the form of medicine, and whether it is taken alone or with other medicines. It is important to follow the exact directions given to you by your doctor.
- Always check the appearance of the capsules with the pharmacist when the prescription is filled to be certain you are given the right medication.

Important questions to ask your doctor:

- Why am I being given this medicine? _____
- What amount should I be taking? _____

What does the drug look like and how should I take it?

Trileptal® Tablets

Available in three strengths:

150 mg (pale gray-green, scored)

300 mg (yellow, scored)

600 mg (light pink, scored)

To take capsules:

- Swallow tablets whole with a glass of water.
- Usually taken two times a day, but may be taken more often.

Trileptal® Suspension/Liquid

5 milliliters (ml) or 1 teaspoon is equal to 300 milligrams (mg).

Trileptal suspension is off-white to slightly brown or red in color.

To take in liquid form:

- Shake the bottle well before using it.
- Use only a special measuring spoon or device to measure the correct dose.
- The liquid dose may be taken alone or mixed with a small amount of water.
- Does not need to be taken with food.

Frequently asked questions:

Is it best to take this medicine with food? This medicine can be taken with food or on an empty stomach. Sometimes taking it with food will lessen stomach upset. Try to take it the same way each day, since taking this with food may change the time it takes to be absorbed. Note: Do not drink grapefruit juice, because it can interfere with the body's use of this medicine.

What should I do if I miss a dose? If you miss or forget a dose take it as soon as possible. However, if you have missed a dose and it is within a few hours before your next dose, take only the next scheduled dose. Do not double up or take extra medicine, unless instructed to do so by your doctor.

How can I remember to take my medicine?

- Take medicine at the same time each day.
- Take at the same time as some other routine, such as brushing teeth, after meals, or bedtime.
- Use a pillbox so you can check if you have taken a dose.
- Use an alarm to remind you of times to take a dose.
- Keep a written schedule or chart of when to take the medicine.
- Talk to your doctor or health care provider about problems remembering the medicine.

How long will it take for the medicine to work? It may take a number of weeks to find the right dose, and then more time may be needed to know how well the medicine works to control your seizures. How long this takes will be different for each person. It may depend on how often you have seizures, what other medicine you may be taking, and how your body responds to the drug.

Should I write down how the medicine is affecting me? It is important to write down how you feel while you are on the medicine. Also keep track of changes in how much medicine is prescribed, side effects, and changes in seizures. Take the information to all follow-up visits with your health care providers.

How should I store my medicine? Store the medicine at room temperature (25° C or 77° F), away from heat, moisture and direct light. Keep it out of the reach of children. Don't keep in the bathroom, glove box of a car, or where children can easily find them, such as in purses or low cabinets or counter top for example. Keep the liquid in its original container and use it within 7 weeks of when you first opened the bottle.

Will this medicine affect other medicines that I am taking? Make sure to tell all your health care providers the names of all medicines, herbal or dietary supplements, vitamins and over-the-counter medicines you may be taking. Some of these medicines may interfere with how oxcarbazepine works and lower or raise the amount in your system. Oxcarbazepine may also affect how other medicines work.

Some medicines that may interact with oxcarbazepine include: hormonal contraceptives, warfarin, and other antiepileptic medicines. Please see AED Interaction Sheets for lists of medicines that may interact with oxcarbazepine. (<http://professionals.epilepsy.com/pdfs/epilepsy-oxcarbazepine-912.pdf>).

What side effects may occur? Side effects may occur with any medicine. Some side effects will go away on their own or when the dose of medicine is changed. Others may be more serious and mean that your body is not tolerating the drug. Tell your doctor about all side effects that occur, but do not stop taking the medicine without advice from your doctor. Some side effects include the following:

Common: Headache, jerking movements of the eyes that may cause double or blurry vision, dizziness, upset stomach, or a low sodium level in the blood (also called hyponatremia).

Potentially serious:

- **Rash:** Not all rashes are caused by the medicine, but all rashes should be reported to your doctor and checked out. Rashes that may be more serious usually begin in the first few weeks, but can happen at any time while you are taking it. Serious rashes may have the following symptoms and require immediate evaluation:
 - Blisters or sores in mouth, eyes, ears, nose, and genital area.
 - Swelling of eyelids or red eyes.
 - Red spots or patches on skin.
 - Fever or flu-like symptoms that don't go away.
- **Other rare side effects:** Vomiting, frequent headaches, and confusion. Rarely, a low sodium concentration in the blood can be associated with confusion, sleepiness, sedation or even coma.

- **Allergic reaction:** May be seen with symptoms such as hives or large red spots on the body, itching, difficulty breathing or closing of the throat. Rare instances of people developing an allergic reaction and swelling of the throat, lips and eyelids have been reported in people after taking the first or later doses of oxcarbazepine. These reactions can be life-threatening and people who have had these reactions should not take the drug again.

When should I call my doctor?

- Call a doctor right away if any side effects become severe or cause problems in your ability to function, or if you have any of the following problems: confusion, frequent headaches, vomiting, rash, allergic reaction.
- Do not stop the medicine without talking to a doctor first.

Can this seizure medicine affect bone health? Some seizure medicines can cause thinning of the bones and lead to bone loss. People taking this medicine should take calcium and vitamin D supplements each day. Regular exercise and diet are also very important. People who have thinning of the bones may also need to take prescription medicines to treat this. Talk to your doctor about tests to check the health of your bones and what to do next.

Can I drink alcohol while on this medicine? People taking this medicine should not drink alcohol, because oxcarbazepine can increase the effects of alcohol.

May I drive while taking oxcarbazepine? Use caution when driving, operating machinery, or performing other hazardous activities. Oxcarbazepine may cause dizziness and double vision. If you have these problems or are having seizures, avoid these activities and talk to your doctor.

Just for Women:

Is this medicine safe to take during pregnancy? Oxcarbazepine has an FDA pregnancy category of “C” meaning that the benefits of taking the medicine may outweigh the risks of harming the fetus. If you find or suspect that you are pregnant, continue use of this medicine and contact your doctor right away. Talk to your doctor about the potential benefits and risks before making any decisions about use of this medicine. Seizures can be harmful to the mother and the developing baby but these can be lessened with proper care.

Does this medicine affect birth control pills? Contraceptives or birth control that contain the hormones estrogen or progesterone (such as birth control pills, injections or patches) may not work completely to prevent pregnancy when a woman is also taking oxcarbazepine. The dose of contraceptive may need to be increased or injections given more frequently. Talk to your doctor if you start or stop hormonal birth control and for specific instructions on the dose of birth control. Other forms of birth control, such as barrier methods, may also be suggested. Call your doctor if you have any signs of breakthrough bleeding or symptoms of pregnancy.

Will the medicine affect my menstrual cycle? This medicine should not affect the menstrual cycle. If your cycle becomes irregular, call your doctor.

Can I breast feed while taking this medicine? In general, women taking oxcarbazepine can breastfeed while using this medicine. However, the drug does pass through breast milk in small amounts. According to the American Academy of Neurology, the benefits for the infant and mother are believed to outweigh the risks for adverse effects. Talk to your doctor regarding this option.

Are there any specific vitamins I should be taking? All women who could possibly get pregnant should be taking at least 0.4 milligrams (mg) of folic acid or folate each day. Women taking some seizure medicines may need to take a higher dose of folic acid, up to 4 mg each day. Speak to your health care provider for specific instructions. Folic acid is also found in leafy dark green vegetables, fruits and juices, and lentils.

More questions?

For more detailed information about oxcarbazepine and seizures, please visit www.epilepsy.com and click on Treatment >> Seizure Medicines (www.epilepsy.com/epilepsy/seizure_medicines.html).

On July 10, 2008, an advisory panel was convened by the Food and Drug Administration (FDA) to review data that the FDA had previously collected from drug studies showing an association between many of the antiepileptic drugs (AEDs) and suicidal ideation and behavior, which together are called suicidality. According to the FDA's Alert, among the patients with epilepsy in these drug studies, 1 out of 1000 people taking the placebo (inactive substance) showed suicidality compared to approximately 3.5 out of 1000 people who took an AED. The FDA advisory panel voted to accept the FDA's data at its meeting on July 10.

The FDA has provided the following information for patients, family members, and caregivers at www.fda.gov/cder/drug/InfoSheets/HCP/antiepilepticsHCP.htm:

- Taking antiepileptic medicines may increase the risk of having suicidal thoughts or actions;
- Do not make any changes to the medication regimen without first talking with the responsible healthcare professional;
- Pay close attention to any day-to-day changes in mood, behavior and actions. These changes can happen very quickly so it is important to be mindful of any sudden differences.
- Be aware of common warning signs that might be a signal for risk of suicide. Some of these are:
 - Talking or thinking about wanting to hurt yourself or end your life
 - Withdrawing from friends and family
 - Becoming depressed or having your depression get worse
 - Becoming preoccupied with death and dying
 - Giving away prized possessions

We again urge patients and families to contact their doctor before stopping an epilepsy medication because this may possibly lead to seizures and worsening of mood.