

MEDICATION GUIDE

Oxtellar XR™ ((ahks-TEH-lahr eks ahr)) (oxcarbazepine) Extended-Release Tablets

Read this Medication Guide before you start taking Oxtellar XR™ and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about Oxtellar XR™?

Do not stop taking Oxtellar XR™ without first talking to your healthcare provider.

Stopping Oxtellar XR™ suddenly can cause serious problems.

Oxtellar XR™ can cause serious side effects, including:

1. Oxtellar XR™ 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 Oxtellar XR™. 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.

2. Oxtellar XR™ 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 Oxtellar XR™. Tell your healthcare provider if you are allergic to carbamazepine.

3. Like other antiepileptic drugs, Oxtellar XR™ may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call your 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 Oxtellar XR™ without first talking to a healthcare provider.

Stopping Oxtellar XR™ 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 Oxtellar XR™?

Oxtellar XR™ is a prescription medicine used:

- with other medicines to treat partial seizures in adults
- with other medicines to treat partial seizures in children 6 to 17 years of age.

It is not known if Oxtellar XR™ is safe and effective in children under 6 years of age.

Who should not take Oxtellar XR™?

- Do not take Oxtellar XR™ if you are allergic to oxcarbazepine or any of the other ingredients in Oxtellar XR™. See the end of this leaflet for a complete list of ingredients in Oxtellar XR™.

What should I tell my healthcare provider before taking Oxtellar XR™?

Before taking Oxtellar XR™, 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
- use birth control medicine. Oxtellar XR™ 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. Oxtellar XR™ may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking Oxtellar XR™. You and your healthcare provider will decide if you should take Oxtellar XR™ while you are pregnant.
 - If you become pregnant while taking Oxtellar XR™, talk to your healthcare provider about registering with the North American 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. Oxtellar XR™ passes into breast milk. You and your healthcare provider should discuss whether you should take Oxtellar XR™ or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking Oxtellar XR™ 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.

Especially tell your healthcare provider if you take: carbamazepine, phenobarbital, phenytoin, or birth control medicine.

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take Oxtellar XR™?

Do not stop taking Oxtellar XR™ without talking to your healthcare provider. Stopping Oxtellar XR™ suddenly can cause serious problems, including seizures that will not stop (status epilepticus). Take Oxtellar XR™ exactly as prescribed. Your healthcare provider may change your dose. Your healthcare provider will tell you how much Oxtellar XR™ to take.

Take Oxtellar XR™ 1 time each day.

Take Oxtellar XR™ on an empty stomach. This means you should take Oxtellar XR™ at least 1 hour before or at least 2 hours after a meal. Take Oxtellar XR™ tablets whole with water or other liquid.

Do not cut, crush, or chew the tablets before swallowing.

If you take too much Oxtellar XR™ call your healthcare provider or call the poison control center at 1-800-222-1222.

Take Oxtellar XR™ at the same time each day.

Talk with your healthcare provider about what you should do if you miss a dose.

What should I avoid while taking Oxtellar XR™?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how Oxtellar XR™ affects you. Oxtellar XR™ may slow your thinking and motor skills.
- Do not drink alcohol or take other drugs that make you sleepy or dizzy while taking Oxtellar XR™ until you talk to your healthcare provider. Oxtellar XR™ taken with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

What are the possible side effects of Oxtellar XR™?

See **“What is the most important information I should know about Oxtellar XR™?”**

Oxtellar XR™ may cause other serious side effects including:

- your seizures can happen more often or become worse
- trouble concentrating
- problems with your speech and language
- feeling confused
- feeling sleepy and tired
- trouble walking and with coordination

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 Oxtellar XR™?”

The most common side effects of Oxtellar XR™ include:

- dizziness
- sleepiness
- headache
- problems with walking and coordination (unsteadiness)

- shakiness
- nausea
- vomiting
- double vision
- weakness
- tiredness

These are not all the possible side effects of Oxtellar XR™. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effect that bothers you or 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 Oxtellar XR™?

- Store Oxtellar XR™ at room temperature 68°F to 77°F (20°C and 25°C)
- Keep Oxtellar XR™ in a tightly closed container, and keep Oxtellar XR™ out of the light.
- Keep Oxtellar XR™ tablets dry.

Keep Oxtellar XR™ and all medicines out of the reach of children.

General Information about the safe and effective use of Oxtellar XR™

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Oxtellar XR™ for a condition for which it was not prescribed. Do not give Oxtellar XR™ to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Oxtellar XR™. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for the full prescribing information about Oxtellar XR™ that is written for health professionals.

For more information, go to www.supernus.com or call 1-866-398-0833.

What are the ingredients in Oxtellar XR™?

Active ingredient: oxcarbazepine

Inactive ingredients:

150 mg tablets: colloidal silicon dioxide, hypromellose, yellow iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, sodium lauryl sulfate, talc, and titanium dioxide.

300 mg tablets: colloidal silicon dioxide, hypromellose, yellow iron oxide, red iron oxide, black iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, sodium lauryl sulfate, talc, and titanium dioxide.

600 mg tablets: red iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, sodium lauryl sulfate, talc, and titanium dioxide.

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

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