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17.2 Medication Guide

Medication Guide Oleptro™ (Oh-LEP-troe) (trazodone hydrochloride) extended-release tablets

Read the Medication Guide that comes with Oleptro before you start taking it 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. Talk to your healthcare provider or pharmacist if there is something you do not understand or you want to learn about Oleptro.

What is the most important information I should know about Oleptro?

Antidepressant medicines, depression or other serious mental illnesses, and suicidal thoughts or actions:

Talk to your healthcare provider about:

- All risks and benefits of treatment with antidepressant medicines
 - All treatment choices for depression or other serious mental illnesses
1. **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
 2. **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a higher risk of having suicidal thoughts or actions.** These include people who have or have a family history of bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
 3. **How can I watch for and try to prevent suicidal thoughts and actions?**
 - Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
 - Call your healthcare provider right away to report new or sudden changes in mood, behavior, 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.

Call a healthcare provider right away if you have any of the following 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 very 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

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
 - **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider, not just the use of antidepressants.
 - **Antidepressant medicines have other side effects.** Talk to your healthcare provider about the side effects of your medicines.
 - **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you take. Keep a list of all medicines to show your healthcare provider. Do not start new medicines without first checking with your healthcare provider.
4. **Oleptro is not approved for use in children.** Talk to your healthcare provider for more information.

What is Oleptro?

Oleptro is a prescription medicine taken 1 time a day to treat major depressive disorder in adults.

Who should not take Oleptro?

- If you take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
- Do not take an MAOI within 2 weeks of stopping Oleptro unless directed to do so by your physician.
- Do not start Oleptro if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

What should I tell my healthcare provider before taking Oleptro?

Before you take Oleptro, tell your healthcare provider if you:

- Have heart problems, including QT prolongation or a family history of it
- Have ever had a heart attack
- Have bipolar disorder
- Have liver or kidney problems
- Have other serious medical conditions
- Are pregnant or plan to become pregnant. Oleptro may harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. It is not known if Oleptro passes into your breast milk. You and your healthcare provider should decide if you will take Oleptro or breastfeed.

- Have taken a Monoamine Oxidase Inhibitor (MAOI) or if you have stopped taking an MAOI in the last 2 weeks.

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

Using Oleptro with certain other medicines can affect each other causing serious side effects.

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 Oleptro?

- Take Oleptro exactly as your healthcare provider tells you.
- Oleptro should be taken 1 time a day.
- Oleptro should be taken at the same time each day in the late evening, if possible at bedtime, on an empty stomach.
- Do not stop taking Oleptro without talking to your healthcare provider.
- Oleptro should be swallowed whole or broken in half along the score line. Do not chew or crush Oleptro. Tell your healthcare provider if you cannot swallow Oleptro either whole or as a half tablet

What should I avoid while taking Oleptro?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how Oleptro affects you. Oleptro can slow your thinking and motor skills.
- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking Oleptro until you talk with your healthcare provider. Oleptro may make your sleepiness or dizziness worse if you take it with alcohol or other medicines that cause sleepiness or dizziness.

What are the possible side effects of Oleptro?

Oleptro can cause serious side effects or death. See “What is the most important information I should know about Oleptro?”

Serious side effects include:

- Serotonin syndrome. Symptoms of serotonin syndrome include: agitation, hallucinations, problems with coordination, fast heartbeat, tight muscles, trouble walking, nausea, vomiting, diarrhea.
- Visual problems
 - eye pain
 - changes in vision
 - swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

- Feeling high or in a very good mood, then becoming irritable, or having too much energy, feeling like you have to keep talking or do not sleep (Mania).
- Irregular or fast heartbeat or faint (QT prolongation).
- Low blood pressure. You feel dizzy or faint when you change positions (go from sitting to standing).
- Unusual bruising or bleeding.
- Erection lasting for more than 6 hours (Priapism).
- Low sodium in your blood (Hyponatremia). Symptoms of hyponatremia include: headache, feeling weak, feeling confused, trouble concentrating, memory problems and feeling unsteady when you walk.

Get medical help right away, if you have any of the symptoms listed above.

The most common side effects of Oleptro include:

- Sleepiness
- Dizziness
- Constipation
- Blurry vision

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

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 Oleptro?

- Store Oleptro between 59°F to 86°F (15°C to 30°C)
- Keep in tight container
- Keep out of the light

Keep Oleptro and all medicines out of the reach of children.

General information about Oleptro.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Oleptro for a condition for which it was not prescribed. Do not give Oleptro 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 Oleptro. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Oleptro that is written for health professionals.

For more information, go to www.oleptro.com or call 1-877-345-6177.

What are the ingredients in Oleptro?

Active ingredient: trazodone hydrochloride

Inactive ingredients: hydroxypropyl distarch phosphate (Contramid[®]), hypromellose, sodium stearyl fumarate, colloidal silicon dioxide, iron oxide yellow, iron oxide red, talc, polyethylene glycol 3350, titanium dioxide, polyvinyl alcohol, black ink (food grade).

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



Angelini Pharma Inc.
Gaithersburg, MD 20877

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