

17.2 FDA-Approved Medication Guide

Medication Guide Escitalopram Tablets (es" sye tal' oh pram)

Read the Medication Guide that comes with escitalopram before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

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

Escitalopram and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **Escitalopram and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults within the **first few months of treatment or when the dose is changed**.
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
- Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when escitalopram is started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. Escitalopram may be associated with these serious side effects:

2. Serotonin Syndrome. This condition can be life-threatening and may include:

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity

3. Severe allergic reactions:

- trouble breathing
- swelling of the face, tongue, eyes or mouth
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

4. Abnormal bleeding:

Escitalopram and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin®, Jantoven®), a non-steroidal anti-inflammatory drug (NSAIDs, like ibuprofen or naproxen), or aspirin.

5. Seizures or convulsions

6. Manic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

7. Changes in appetite or weight.

Children and adolescents should have height and weight monitored during treatment.

8. Low salt (sodium) levels in the blood.

Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

9. 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.

Do not stop escitalopram without first talking to your healthcare provider.

Stopping escitalopram too quickly may cause serious symptoms including:

- anxiety, irritability, high or low mood, feeling restless or changes in sleep habits
- headache, sweating, nausea, dizziness
- electric shock-like sensations, shaking, confusion

What is escitalopram?

Escitalopram is a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider. Escitalopram is also used to treat:

- Major Depressive Disorder (MDD)
- Generalized Anxiety Disorder (GAD)

Talk to your healthcare provider if you do not think that your condition is getting better with escitalopram treatment.

Who should not take escitalopram?

Do not take escitalopram if you:


- are allergic to escitalopram oxalate or citalopram hydrobromide or any of the ingredients in escitalopram tablets. See the end of this Medication Guide for a complete list of ingredients in escitalopram tablets.
- 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 escitalopram unless directed to do so by your physician.
- Do not start escitalopram if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take escitalopram close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- high fever
- uncontrolled muscle spasms
- stiff muscles
- rapid changes in heart rate or blood pressure
- confusion
- loss of consciousness (pass out)

Last modified: 7. February 2017, 2:05 PM

■ Black

| | | |
|--|---|---|
| Reason for Artwork: RLD update "LEXAPRO" (dated: 01/04/2017) |  | Dimension: 280 x 216 mm |
| Item Code: 5000002259 | JUBILANT GENERICS | Superseded Item Code: 7524000530 |
| Substrate: 40 GSM Bible paper | | |
| Site Packaging Development Sign and Date | Production Sign and Date | QA Sign and Date |

- take the antipsychotic medicine pimozide (Orap®) because taking this drug with escitalopram can cause serious heart problems.

What should I tell my healthcare provider before taking escitalopram?

Ask if you are not sure.

Before starting escitalopram, tell your healthcare provider if you:

- Are taking certain drugs such as:
 - Triptans used to treat migraine headache
 - Medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, SSRIs, SNRIs, amphetamines, or antipsychotics
 - Tramadol
 - Over-the-counter supplements such as tryptophan or St. John's Wort
- have liver problems
- have kidney problems
- have heart problems
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have a history of a stroke
- have high blood pressure
- have or had bleeding problems
- are pregnant or plan to become pregnant. It is not known if escitalopram will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy
- are breast-feeding or plan to breast-feed. Some escitalopram may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking escitalopram.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Escitalopram and some medicines may interact with each other, may not work as well, or may cause serious side effects. Your healthcare provider or pharmacist can tell you if it is safe to take escitalopram with your other medicines. Do not start or stop any medicine while taking escitalopram without talking to your healthcare provider first.

If you take escitalopram, you should not take any other medicines that contain escitalopram oxalate or citalopram hydrobromide including: Celexa.

How should I take escitalopram?

- Take escitalopram exactly as prescribed. Your healthcare provider may need to change the dose of escitalopram until it is the right dose for you.
- Escitalopram may be taken with or without food.
- If you miss a dose of escitalopram, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of escitalopram at the same time.
- If you take too much escitalopram, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking escitalopram?

Escitalopram can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how escitalopram affects you. Do not drink alcohol while using escitalopram.

What are the possible side effects of escitalopram?

Escitalopram may cause serious side effects, including all of those described in the section entitled "What is the most important information I should know about escitalopram?"

Common possible side effects in people who take escitalopram include:

- Nausea
- Sleepiness
- Weakness
- Dizziness

- Feeling anxious
- Trouble sleeping
- Sexual problems
- Sweating
- Shaking
- Not feeling hungry
- Dry mouth
- Constipation
- Infection
- Yawning

Other side effects in children and adolescents include:

- increased thirst
- abnormal increase in muscle movement or agitation
- nose bleed
- difficult urination
- heavy menstrual periods
- possible slowed growth rate and weight change. Your child's height and weight should be monitored during treatment with escitalopram.

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 escitalopram. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088.

How should I store escitalopram tablets?

- Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
- Keep escitalopram tablets bottle closed tightly.

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

General information about escitalopram

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

This Medication Guide summarizes the most important information about escitalopram. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about escitalopram that is written for healthcare professionals.

For more information, call toll-free 1-800-313-4623.

What are the ingredients in escitalopram tablets?

Active ingredient: escitalopram oxalate, USP
 Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and talc. The film coating contains polyethylene glycol, hypromellose, and titanium dioxide.
 The following are registered trademarks of their respective manufacturers and are not trademarks of Jubilant Generics Limited: Celexa®, Coumadin®, Jantoven® and Orap®.

Rx Only

Manufactured by:
 Jubilant Generics Limited
 Roorkee - 247661, India


Marketed by:
 Jubilant Cadista Pharmaceuticals Inc.
 Salisbury, MD 21801, USA

Revised: 02/2017

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

5000002259

Neutral Code No. UK/Drugs/68/UA/2007

| | | | | | |
|--|--|---|---|-------------------------|--|
| Reason for Artwork: RLD update "LEXAPRO" (dated: 01/04/2017) | |  | Dimension: 280 x 216 mm | | |
| Item Code: 5000002259 | | | Superseded Item Code: 7524000530 | | |
| Substrate: 40 GSM Bible paper | | | | | |
| Site Packaging Development Sign and Date | | Production Sign and Date | | QA Sign and Date | |