

Medication Guide Escitalopram Oral Solution, USP (es’ sye tal’ oh pram)		
<p><b>What is the most important information I should know about escitalopram oral solution?</b></p> <p><b>Escitalopram oral solution may cause serious side effects, including:</b></p> <ul style="list-style-type: none"><li>• <b>Increased risk of suicidal thoughts or actions.</b> Escitalopram oral solution and other antidepressant medicines increase the risk of suicidal thoughts and actions in people 24 years of age and younger, <b>especially within the first few months of treatment or when the dose is changed.</b><ul style="list-style-type: none"><li>○ <b>Depression or other mental illnesses are the most important causes of suicidal thoughts or actions.</b></li></ul></li></ul> <p><b>How can I watch for and try to prevent suicidal thoughts and actions?</b></p> <ul style="list-style-type: none"><li>○ Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you or your child develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.</li><li>○ Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings or if you or your child develop suicidal thoughts or actions.</li><li>○ Keep all follow-up visits with your healthcare provider as scheduled and call your healthcare provider between visits if you are worried about symptoms.</li></ul> <p><b>Call your healthcare provider or get emergency medical help right away if you or your child have any of the following symptoms, especially if they are new, worse, or worry you:</b></p> <table><tr><td><ul style="list-style-type: none"><li>• attempts to commit suicide</li><li>• acting aggressive, being angry or violent</li><li>• new or worse depression</li><li>• panic attacks</li><li>• new or worse irritability</li><li>• an extreme increase in activity or talking (mania)</li></ul></td><td><ul style="list-style-type: none"><li>• acting on dangerous impulses</li><li>• thoughts about suicide or dying</li><li>• new or worsening anxiety</li><li>• feeling very agitated or restless</li><li>• trouble sleeping</li><li>• other unusual changes in behavior or mood</li></ul></td></tr></table>	<ul style="list-style-type: none"><li>• attempts to commit suicide</li><li>• acting aggressive, being angry or violent</li><li>• new or worse depression</li><li>• panic attacks</li><li>• new or worse irritability</li><li>• an extreme increase in activity or talking (mania)</li></ul>	<ul style="list-style-type: none"><li>• acting on dangerous impulses</li><li>• thoughts about suicide or dying</li><li>• new or worsening anxiety</li><li>• feeling very agitated or restless</li><li>• trouble sleeping</li><li>• other unusual changes in behavior or mood</li></ul>
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<p><b>What is escitalopram oral solution?</b></p> <p>Escitalopram oral solution is a prescription medicine used to treat:</p> <ul style="list-style-type: none"><li>• a certain type of depression called Major Depressive Disorder (MDD) in adults and children 12 years of age and older</li><li>• Generalized Anxiety Disorder (GAD) in adults</li></ul> <p>It is not known if escitalopram oral solution is safe and effective for use in children under 12 years of age with MDD or children under 7 years of age with GAD.</p>		
<p><b>Do not take escitalopram oral solution if you or your child:</b></p> <ul style="list-style-type: none"><li>• are taking, or have stopped taking within the last 14 days, a medicine called a monoamine oxidase inhibitor (MAOI), including the antibiotic linezolid or intravenous methylene blue</li><li>• are taking the antipsychotic medicine pimozide</li><li>• are allergic to escitalopram or citalopram or any of the ingredients in escitalopram oral solution. See the end of this Medication Guide for a complete list of ingredients in escitalopram oral solution.</li></ul> <p>Ask your healthcare provider or pharmacist if you are not sure if you or your child take an MAOI, including the antibiotic linezolid or intravenous methylene blue.</p> <p><b>Do not start taking an MAOI for at least 14 days after you or your child have stopped treatment with escitalopram oral solution.</b></p>		
<p><b>Before taking escitalopram oral solution, tell your healthcare provider about all your medical conditions, including if you or your child:</b></p> <ul style="list-style-type: none"><li>• have or had seizures or convulsions</li><li>• have, or have a family history of bipolar disorder, mania, or hypomania</li><li>• have low blood sodium levels</li><li>• have or had bleeding problems</li><li>• have high pressure in the eye (glaucoma)</li><li>• have heart, liver, or kidney problems</li><li>• are pregnant or plan to become pregnant. Escitalopram oral solution may harm the unborn baby. Taking escitalopram oral solution during the third trimester of pregnancy may cause the baby to have withdrawal symptoms, or breathing, temperature control, feeding, or other problems after birth. Talk to your healthcare provider about the risks to the baby if you or your child take escitalopram oral solution during pregnancy.<ul style="list-style-type: none"><li>○ Tell your healthcare provider right away if you or your child become pregnant or think you may be pregnant during treatment with escitalopram oral solution.</li><li>○ There is a pregnancy registry for females who are exposed to escitalopram oral solution during pregnancy. The purpose of the registry is to collect information about the health of females exposed to escitalopram oral solution and their baby. If you or your child become pregnant during treatment with escitalopram oral solution, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit online at <a href="https://womensmentalhealth.org/research/pregnancyregistry/antidepressants">https://womensmentalhealth.org/research/pregnancyregistry/antidepressants</a>.</li></ul></li><li>• are breastfeeding or plan to breastfeed. Escitalopram passes into breast milk and may harm the baby. Talk to your healthcare provider about the best way to feed the baby during treatment with escitalopram oral solution.<ul style="list-style-type: none"><li>○ If you or your child breastfeed during treatment with escitalopram oral solution, call your healthcare provider if the baby develops sleepiness or fussiness, or is not feeding or gaining weight well.</li></ul></li></ul> <p><b>Tell your healthcare provider about all the medicines you or your child take,</b> including prescription and non-prescription medicines, vitamins, and herbal supplements.</p> <p>Escitalopram oral solution and some medicines may affect each other and may cause serious side effects.</p> <p>Escitalopram oral solution may affect the way other medicines work and other medicines may affect the way escitalopram oral solution works.</p> <p><b>Especially tell your healthcare provider if you take:</b></p> <ul style="list-style-type: none"><li>• medicines used to treat migraine headache known as triptans</li><li>• tricyclic antidepressants</li><li>• lithium</li><li>• tramadol, fentanyl, meperidine, methadone, or other opioids</li><li>• tryptophan</li><li>• buspirone</li><li>• amphetamines</li><li>• St. John’s Wort</li><li>• medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)</li><li>• diuretics</li><li>• medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) and warfarin</li></ul> <p>Ask your healthcare provider if you are not sure if you or your child are taking any of these medicines. Your healthcare provider can tell you if it is safe to take escitalopram oral solution with your other medicines.</p> <p><b>Do not start or stop any other medicines during treatment with escitalopram oral solution without talking to your healthcare provider first. Stopping escitalopram oral solution suddenly may cause you or your child to have serious side effects. See, “What are the possible side effects of escitalopram oral solution?”</b></p> <p>Know the medicines you or your child take. Keep a list of them to show your healthcare provider and pharmacist when you get new medicine.</p>		
<p><b>How should I take escitalopram oral solution?</b></p> <ul style="list-style-type: none"><li>• Take escitalopram oral solution exactly as prescribed. Your healthcare provider may need to change the dose of escitalopram oral solution until it is the right dose for you or your child.</li><li>• Take escitalopram oral solution 1 time each day, in the morning or the evening.</li><li>• Take escitalopram oral solution with or without food.</li><li>• If you or your child take too much escitalopram oral solution, call your healthcare provider or Poison Help Line at 1-800-222-1222, or go to the nearest hospital emergency room right away.</li></ul>		

What should I avoid while taking escitalopram oral solution?

- **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how escitalopram oral solution affects you. Escitalopram oral solution can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly.
- **Do not** drink alcohol during treatment with escitalopram oral solution.

What are the possible side effects of escitalopram oral solution?

Escitalopram oral solution may cause serious side effects, including:

- See “**What is the most important information I should know about escitalopram oral solution?**”
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when escitalopram oral solution is taken with certain other medicines. See “**Do not take escitalopram oral solution if you?**” **Call your healthcare provider or go to the nearest hospital emergency room right away** if you or your child have any of the following signs and symptoms of serotonin syndrome:
  - agitation
  - confusion
  - fast heartbeat
  - sweating
  - flushing
  - seizures
  - nausea, vomiting, diarrhea
  - seeing or hearing things that are not real (hallucinations)
  - coma
  - blood pressure changes
  - shaking (tremors), stiff muscles, or muscle twitching
  - dizziness
  - high body temperature (hyperthermia)
  - loss of coordination
- **Discontinuation syndrome.** Suddenly stopping escitalopram oral solution may cause you or your child to have serious side effects. Your healthcare provider may want to decrease the dose slowly. Symptoms may include:
  - changes in mood
  - irritability and agitation
  - dizziness
  - electric shock sensation (paresthesia)
  - anxiety
  - confusion
  - headache
  - tiredness
  - problems sleeping
  - hypomania
  - ringing in your ears (tinnitus)
  - seizures
- **Seizures (convulsions).**
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take escitalopram oral solution. Symptoms may include:
  - greatly increased energy
  - racing thoughts
  - unusually grand ideas
  - talking more or faster than usual
  - severe trouble sleeping
  - reckless behavior
  - excessive happiness or irritability
- **Low sodium levels in the blood (hyponatremia).** Low sodium levels in the blood that may be serious and may cause death can happen during treatment with escitalopram oral solution. Elderly people and people who take certain medicines may be at greater risk for developing low sodium levels in the blood. Signs and symptoms may include:
  - headache
  - weakness or feeling unsteady which can lead to falls
  - memory problems
  - problems concentrating or thinking
  - confusion
- **In more severe or more sudden cases, signs and symptoms include:**
  - seeing or hearing things that are not real (hallucinations)
  - seizures
  - stopping breathing (respiratory arrest)
  - fainting
  - coma
- **Increased risk of bleeding:** Taking escitalopram oral solution with aspirin, NSAIDS, warfarin, or other blood thinners may add to this risk. Tell your healthcare provider if you have any unusual bleeding or bruising.
- **Visual problems (angle-closure glaucoma).** Escitalopram oral solution may cause a type of eye problem called angle-closure glaucoma in people with certain eye problems. You or your child may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your healthcare provider if you or your child have:
  - eye pain
  - changes in vision
  - swelling or redness in or around the eye
- **Sexual problems (dysfunction).** Taking escitalopram oral solution may cause sexual problems. Symptoms in males may include:
  - delayed ejaculation or inability to have an ejaculation
  - problems getting or keeping an erectionSymptoms in females may include:
  - decreased sex drive
  - delayed orgasm or inability to have an orgasmTalk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with escitalopram oral solution. There may be treatments your healthcare provider can suggest.
- **The most common side effects of escitalopram oral solution include:**
  - trouble sleeping
  - delayed ejaculation
  - nausea
  - sweating
  - tiredness
  - sleepiness
  - decreased sex drive
  - delayed orgasm or inability to have an orgasm

Height and weight changes in children may happen during treatment with escitalopram oral solution. Your child’s height and weight should be monitored during treatment with escitalopram oral solution.  
These are not all the possible side effects of escitalopram oral solution.  
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 escitalopram oral solution?

- Store escitalopram oral solution at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep escitalopram oral solution and all medicines out of the reach of children.**

General information about the safe and effective use of escitalopram oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use escitalopram oral solution for a condition for which it was not prescribed. Do not give escitalopram oral solution to other people, even if they have the same symptoms that you have. It may harm them. You may ask your pharmacist or healthcare provider for information about escitalopram oral solution that is written for health professionals.

What are the ingredients in escitalopram oral solution?

**Active ingredient:** escitalopram oxalate

**Inactive ingredients:**

**Oral Solution:** anhydrous citric acid, glycerin, malic acid, methylparaben, natural peppermint flavor, non-crystallizing sorbital solution, propylene glycol, propylparaben, purified water and sodium citrate dihydrate.

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*Additional pediatric use information is approved for AbbVie Inc.’s LEXAPRO (escitalopram) oral solution. However, due to AbbVie Inc.’s marketing exclusivity rights, this drug product is not labeled with that information.*