Medication Guide

Escitalopram Tablets, USP

(ES-sye-TAL-oh-pram)

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

Escitalopram tablets may cause serious side effects, including:

- **Increased risk of suicidal thoughts or actions.** Escitalopram tablets and other antidepressant medicines increase the risk of suicidal thoughts and actions in people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed.**
  - **Depression or other mental illnesses are the most important causes of suicidal thoughts or actions.**

  How can I watch for and try to prevent suicidal thoughts and actions?

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

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:

- attempts to commit suicide
- acting aggressive, being angry or violent
- new or worse depression
- panic attacks
- new or worse irritability
- an extreme increase in activity or talking (mania)
- acting on dangerous impulses
- thoughts about suicide or dying
- new or worsening anxiety
- feeling very agitated or restless
- trouble sleeping
- other unusual changes in behavior or mood

What are escitalopram tablets?

Escitalopram tablets are a prescription medicine used to treat:

- a certain type of depression called Major Depressive Disorder (MDD) in adults and children 12 years of age and older
- Generalized Anxiety Disorder (GAD) in adults and children 7 years of age and older

It is not known if escitalopram tablets are safe and effective for use in children under 12 years of age with MDD or children under 7 years of age with GAD.

Do not take escitalopram tablets if you or your child:

- 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
- are taking the antipsychotic medicine pimozide
- are allergic to escitalopram or citalopram or any of the ingredients in escitalopram tablets. See the end of this Medication Guide for a complete list of ingredients in escitalopram tablets.

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.

Do not start taking an MAOI for at least 14 days after you or your child have stopped treatment with escitalopram tablets.

Before taking escitalopram tablets, tell your healthcare provider about all your medical conditions, including if you or your child:

- have or had seizures or convulsions
- have, or have a family history of bipolar disorder, mania, or hypomania
- have low blood sodium levels
- have or had bleeding problems
- have high pressure in the eye (glaucoma)
- have heart, liver, or kidney problems
- are pregnant or plan to become pregnant. Escitalopram tablets may harm the unborn baby. Taking escitalopram tablets 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 tablets during pregnancy.

- Tell your healthcare provider right away if you or your child become pregnant or think you may be pregnant during treatment with escitalopram tablets.

- 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 tablets.

  - If you or your child breastfeed during treatment with escitalopram tablets, call your healthcare provider if the baby develops sleepiness or fussiness, or is not feeding or gaining weight well.

Tell your healthcare provider about all the medicines you or your child take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Escitalopram tablets and some medicines may affect each other and may cause serious side effects.

Escitalopram tablets may affect the way other medicines work and other medicines may affect the way escitalopram tablets work.

Especially tell your healthcare provider if you take:

- medicines used to treat migraine headache known as triptans
- tricyclic antidepressants
- lithium
- tramadol, fentanyl, meperidine, methadone, or other opioids
- tryptophan
- buspirone
- amphetamines
- St. John's Wort
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)
- diuretics
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) and warfarin

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 tablets with your other medicines.

Do not start or stop any other medicines during treatment with escitalopram tablets without talking to your healthcare provider first. Stopping escitalopram tablets suddenly may cause you or your child to have serious side effects. See, **"What are the possible side effects of escitalopram tablets?"**

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.

How should I take escitalopram tablets?

- Take escitalopram tablets exactly as prescribed. Your healthcare provider may need to change the dose of escitalopram tablets until it is the right dose for you or your child.
- Take escitalopram tablets 1 time each day, in the morning or the evening.
- Take escitalopram tablets with or without food.
- If you or your child take too much escitalopram tablets, call your healthcare provider or Poison Help Line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What should I avoid while taking escitalopram tablets?

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

What are the possible side effects of escitalopram tablets?

Escitalopram tablets may cause serious side effects, including:

- See **"What is the most important information I should know about escitalopram tablets?"**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when escitalopram tablets are taken with certain other medicines. See **"Do not take escitalopram tablets 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
  - 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)

- nausea, vomiting, diarrhea
- loss of coordination

- **Discontinuation syndrome.** Suddenly stopping escitalopram tablets 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 tablets. 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 tablets. 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 tablets 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 tablets 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 tablets may cause sexual problems. Symptoms in males may include:
    - delayed ejaculation or inability to have an ejaculation
    - decreased sex drive
    - problems getting or keeping an erection

    Symptoms in females may include:
    - decreased sex drive
    - delayed orgasm or inability to have an orgasm

    Talk 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 tablets. There may be treatments your healthcare provider can suggest.

The most common side effects of escitalopram tablets include:

- trouble sleeping
- sweating
- decreased sex drive
- delayed ejaculation
- tiredness
- delayed orgasm or inability to have an orgasm
- nausea
- sleepiness

Height and weight changes in children may happen during treatment with escitalopram tablets. Your child's height and weight should be monitored during treatment with escitalopram tablets.

These are not all the possible side effects of escitalopram tablets.

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 tablets?

- Store escitalopram tablets at room temperature between 68°F to 77°F (20°C to 25°C).

- **Keep escitalopram tablets and all medicines out of the reach of children.**

General information about the safe and effective use of escitalopram tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use escitalopram tablets for a condition for which it was not prescribed. Do not give escitalopram tablets 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 tablets that is written for health professionals.

What are the ingredients in escitalopram tablets?

Active ingredient: escitalopram oxalate, USP

Inactive ingredients:

Tablets: colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc and a white dye film coating agent. The white dye film coating agent contains the following ingredients: hypromellose, polydextrose, polyethylene glycol, triacetin, and titanium dioxide.

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