

Citalopram_Medguide (Front)

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Citalopram_Medguide (Back)

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**MEDICATION GUIDE
CITALOPRAM (si TAL o pram), USP
(Citalopram)
Tablets, for oral use**

**What is the most important information I should know about citalopram tablets?
Citalopram tablets may cause serious side effects, including:**

- **Increased risk of suicidal thoughts and actions.** Citalopram tablets and other antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults **especially within the first few months of treatment or when the dose is changed. Citalopram tablets are not for use in children.**
 - Depression and other mental illnesses are the most important causes of suicidal thoughts and actions.

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you 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.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call your healthcare provider or get emergency medical help right away if you or your family member 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
- acting on dangerous impulses
- trouble sleeping (insomnia)
- panic attacks
- acting aggressive, being angry, or violent
- new or worse irritability
- an extreme increase in activity or talking (mania)
- other unusual changes in behavior or mood

What are citalopram tablets?
Citalopram tablets are a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD) in adults. It is not known if citalopram tablets are safe and effective for use in children.

**Who should not take citalopram tablets?
Do not take citalopram tablets if you:**

- take a Monoamine Oxidase Inhibitor (MAOI)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or intravenous methylene blue
- take pimozide
- are allergic to citalopram or any of the ingredients in citalopram tablets. See the end of this Medication Guide for a complete list of ingredients in citalopram tablets.

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including MAOIs such as linezolid or intravenous methylene blue.
Do not start taking an MAOI for at least 14 days after you stop treatment with citalopram tablets.

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

- have or have a family history of suicide, depression, bipolar disorder, mania or hypomania
- have an abnormal heart rhythm called QT prolongation
- have or had heart problems, including a heart attack, heart failure, abnormal heart rhythm, or long QT syndrome
- have low potassium, magnesium, or sodium levels in your blood

- have or had bleeding problems
- have or had seizures (convulsions)
- have high pressure in the eye (glaucoma)
- have or had kidney or liver problems
- are pregnant or plan to become pregnant. Citalopram tablets may harm your unborn baby. Taking citalopram tablets late in pregnancy may lead to an increased risk of certain problems in your newborn. Talk to your healthcare provider about the risks and benefits of treating depression during pregnancy.

- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with citalopram tablets.
- There is a pregnancy registry for females who are exposed to citalopram during pregnancy. The purpose of the registry is to collect information about the health of females exposed to citalopram and their baby. If you become pregnant during treatment with citalopram tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185 or visiting online at <https://womensmentalhealth.org/research/pregnancyregistry/antidepressants>.

- are breastfeeding or plan to breastfeed. It is not known if citalopram passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with citalopram tablets.
- If you breastfeed during treatment with citalopram tablets, call your healthcare provider right away if your baby develops sleepiness or fussiness, or is not feeding or gaining weight well.

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

Citalopram tablets and other medicines may affect each other causing possible serious side effects. Citalopram tablets may affect the way other medicines work and other medicines may affect the way citalopram tablets work.

Especially tell your healthcare provider if you take:

- medicines used to treat migraine headaches known as triptans
- tricyclic antidepressants
- lithium
- tramadol, fentanyl, meperidine, methadone, or other opioids
- tryptophan
- buspirone
- amphetamines
- St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) and warfarin

- diuretics
- methadone
- gatifloxacin or moxifloxacin
- medicines used to control your heart rate or rhythm (antiarrhythmics)
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take citalopram tablets with your other medicines.

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

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

How should I take citalopram tablets?

- Take citalopram tablets exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking citalopram tablets without first talking to your healthcare provider.
- Your healthcare provider may need to change the dose of citalopram tablets until it is the right dose

for you.

- Take citalopram tablets 1 time each day with or without food.
- If you take too many citalopram tablets, call your healthcare provider or poison control center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

**What are the possible side effects of citalopram tablets?
Citalopram tablets may cause serious side effects, including:**

- See, **"What is the most important information I should know about citalopram tablets?"**

- **Heart rhythm problems.** Citalopram tablets may cause a serious change in your heartbeat (a fast or irregular heartbeat) that may cause death. Tell your healthcare provider right away if you feel faint or pass out, or if you have a change in your heart beat.

- **Serotonin syndrome.** Taking citalopram tablets can cause a potentially life-threatening problem called serotonin syndrome. The risk of developing serotonin syndrome is increased when citalopram tablets are taken with certain other medicines. See, **"Who should not take citalopram tablets?" Call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:
 - agitation
 - seeing or hearing things that are not real (hallucinations)
 - confusion
 - coma
 - fast heart beat
 - blood pressure changes
 - dizziness
 - sweating
 - flushing
 - high body temperature (hyperthermia)
 - tremors, stiff muscles, or muscle twitching
 - loss of coordination
 - seizures
 - nausea, vomiting, diarrhea

- **Increased risk of bleeding.** Taking citalopram tablets with aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), warfarin or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take citalopram tablets. Symptoms may include:
 - greatly increased energy
 - severe trouble sleeping
 - racing thoughts
 - reckless behavior
 - unusually grand ideas
 - excessive happiness or irritability
 - talking more or faster than usual

- **Discontinuation syndrome.** Suddenly stopping citalopram tablets may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
 - nausea
 - sweating
 - changes in your mood
 - headache
 - irritability and agitation
 - tiredness
 - dizziness
 - problems sleeping
 - electric shock sensation (paresthesia)
 - hypomania
 - anxiety
 - ringing in your ears (tinnitus)
 - confusion
 - seizures

- **Seizures (convulsions).**
- **Eye problems (angle-closure glaucoma).** Many antidepressant medicines, including citalopram tablets, may cause a certain type of eye problem called angle-closure glaucoma. Call your healthcare provider if you have changes in your vision or eye pain.

- **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood may be serious

and may cause death. Elderly people may be at greater risk for this. Tell your healthcare provider right away if you develop any signs or symptoms of low sodium levels in your blood during treatment with citalopram tablets. Signs and symptoms of low sodium levels in your blood may include:

- headache
- difficulty concentrating
- memory changes
- confusion
- weakness and unsteadiness on your feet which can lead to falls

In severe or more sudden cases, signs and symptoms include:

- hallucinations (seeing or hearing things that are not real)
- fainting
- seizures
- coma
- stopping breathing
- death

- **Sexual problems (dysfunction).** Taking selective serotonin reuptake inhibitors (SSRIs), including citalopram 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 citalopram tablets. There may be treatments your healthcare provider can suggest.

The most common side effect of citalopram tablets is delayed ejaculation.

These are not all the possible side effects of citalopram 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 citalopram tablets?

- Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
- **Keep citalopram tablets and all medicines out of the reach of children.**


General information about the safe and effective use of citalopram tablets

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

What are the ingredients in citalopram tablets?

Active ingredient: citalopram hydrobromide, USP
Inactive ingredients: copovidone, corn starch, croscarmellose sodium, ferric oxide red, ferric oxide yellow, glycerin, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol and titanium dioxide.
For more information about citalopram tablets call 1-800-912-9561.

Manufactured by: Piramal Pharma Limited
Pithampur - 454775, India.

 **Manufactured for:** Torrent Pharma INC.
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