

MEDICATION GUIDE

Citalopram Tablets, USP

Read the Medication Guide that comes with citalopram tablets before you start taking them 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 citalopram tablets?

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

1. Suicidal thoughts or actions:

- **Citalopram tablets 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 citalopram tablets are 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. Citalopram tablets may be associated with these serious side effects:

2. Changes in the electrical activity of your heart (QT prolongation and Torsade de Pointes).

This condition can be life-threatening. The symptoms may include:

- chest pain
- fast or slow heartbeat
- shortness of breath
- dizziness or fainting

3. Serotonin Syndrome or Neuroleptic Malignant Syndrome-like reactions. 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

4. 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

5. Abnormal bleeding: Citalopram tablets 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.

6. Seizures or convulsions

7. 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

8. Changes in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

9. 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

Do not stop citalopram tablets without first talking to your healthcare provider. Stopping citalopram tablets 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 are citalopram tablets?

Citalopram tablets are 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. Citalopram tablets are also used to treat:

- Major Depressive Disorder (MDD)

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

Who should not take citalopram tablets?

Do not take citalopram tablets if you:

- are allergic to citalopram hydrobromide or escitalopram oxalate or any of the ingredients in citalopram tablets. See the end of this Medication Guide for a complete list of ingredients in citalopram 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 14 days of stopping citalopram tablets.
 - Do not start citalopram tablets if you stopped taking an MAOI in the last 14 days.

People who take citalopram tablets 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)
- **take the antipsychotic medicine pimozide (Orap[®]) because this can cause serious heart problems.**
- **have a heart problem including congenital long QT syndrome.**

What should I tell my healthcare provider before taking citalopram tablets?

Ask if you are not sure.

Before starting citalopram tablets, tell your healthcare provider if you

- Are taking certain drugs such as:
 - Medicines for heart problems
 - Medicines that lower your potassium or magnesium levels in your body
 - Cimetidine
 - Triptans used to treat migraine headache

- Medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, SSRIs, SNRIs, 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 citalopram tablets 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 breastfeed. Some citalopram may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking citalopram tablets.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Citalopram tablets 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 citalopram tablets with your other medicines. Do not start or stop any medicine while taking citalopram tablets without talking to your healthcare provider first.

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

How should I take citalopram tablets?

- Take citalopram tablets exactly as prescribed. Your healthcare provider may need to change the dose of citalopram tablets until it is the right dose for you.
- Citalopram tablets may be taken with or without food.
- If you miss a dose of citalopram tablets, 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 citalopram tablets at the same time.
- If you take too much citalopram, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking citalopram tablets?

Citalopram tablets 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 citalopram tablets affect you. Do not drink alcohol while using citalopram tablets.

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?”

Common possible side effects in people who take citalopram tablets include:

- Nausea
- Sleepiness
- Weakness
- Dizziness
- Feeling anxious
- Trouble sleeping
- Sexual problems
- Sweating
- Shaking
- Not feeling hungry
- Dry mouth
- Constipation
- Diarrhea
- Respiratory Infections
- Yawning

Other side effects in children and adolescents include:

- increased thirst
- abnormal increase in muscle movement or agitation
- nose bleed
- urinating more often
- heavy menstrual periods
- possible slowed growth rate and weight change. Your child’s height and weight should be monitored during treatment with citalopram tablets.

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 citalopram tablets. 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 citalopram tablets?

- Store citalopram tablets at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- Keep citalopram tablets bottle closed tightly.

Keep citalopram tablets and all medicines out of the reach of children.

General information about 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 condition. They may harm them.

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

For more information about citalopram tablets call 1-866-850-2876 .

What are the ingredients in citalopram tablets?

Active ingredient: citalopram hydrobromide

Inactive ingredients: copovidone, corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, hypromellose, microcrystalline cellulose, polyethylene glycol, and titanium dioxide. Iron oxides are used as coloring agents in the peach (10 mg) and light pink (20 mg) tablets.

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

Orap[®] is a registered trademark of Teva Pharmaceuticals USA.

Coumadin[®] is a registered trademark of Bristol Myers Squibb.

Jantoven[®] is a registered trademark of Upsher-Smith Laboratories Inc.

Lexapro is a registered trademark of Forest Laboratories Inc.

Manufactured by:

Aurolife Pharma LLC

Dayton, NJ 08810

Manufactured for:

Aurobindo Pharma USA, Inc.

Dayton, NJ 08810

Revised: 09/2011