CELEXA- citalopram hydrobromide tablet
Advanced Rx Pharmacy of Tennessee, LLC

Citalopram Hydrobromide 20mg tablets #60

Medication Guide Section

MEDICATION GUIDE

Medication Guide

Citalopram (si TAL o pram) Tablets, USP

Rx Only

Read the Medication Guide that comes with citalopram tablets 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 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. 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, 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

10. 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.

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

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)

• have a heart problem including congenital long QT syndrome

• Do not take citalopram tablets with Orap® (pimozide) because taking these two drugs together can cause serious heart problems.

take the antipsychotic medicine pimozide 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, 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 citalopram tablets will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy
are breastfeeding 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 or escitalopram 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 tablets, 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 tablet?

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 at 20º to 25°C (68º to 77°F); excursions permitted to 15° to 30°C (59º to 86°F) [see USP Controlled Room Temperature].
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. It 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 1-269-544-2299.

What are the ingredients in citalopram tablets?

Active ingredient: citalopram hydrobromide, USP

Inactive ingredients:

Tablets: copovidone, croscarmellose sodium, ferric oxide red, ferric oxide yellow, glycerin, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, starch, and titanium dioxide.

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

[Logo]

Manufactured by:

TORRENT PHARMACEUTICALS LTD., INDIA.

Manufactured For:

TORRENT PHARMA INC., Basking Ridge, NJ 07920.

8075293 Revised May 2019

Dosage and Administration Section

DOSAGE AND ADMINISTRATION

Citalopram tablets should be administered once daily, in the morning or evening, with or without food.

Initial Treatment

Citalopram tablets (citalopram) should be administered at an initial dose of 20 mg once daily, with an increase to a maximum dose of 40 mg/day at an interval of no less than one week. Doses above 40 mg/day are not recommended due to the risk of QT prolongation. Additionally, the only study pertinent to dose response for effectiveness did not demonstrate an advantage for the 60 mg/day dose over the 40 mg/day dose.

Special Populations

20 mg/day is the maximum recommended dose for patients who are greater than 60 years of age, patients with hepatic impairment, and for CYP2C19 poor metabolizers or those patients taking cimetidine or another CYP2C19 inhibitor.(see WARNINGS)

No dosage adjustment is necessary for patients with mild or moderate renal impairment. Citalopram should be used with caution in patients with severe renal impairment.

Treatment of Pregnant Women During the Third Trimester

Neonates exposed to citalopram and other SSRIs or SNRIs, late in the third trimester, have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding (see PRECAUTIONS). When treating pregnant women with citalopram during the third trimester, the physician should carefully consider the potential risks and benefits of treatment.

Maintenance Treatment

It is generally agreed that acute episodes of depression require several months or longer of sustained pharmacologic therapy. Systematic evaluation of citalopram in two studies has shown that its antidepressant efficacy is maintained for periods of up to 24 weeks following 6 or 8 weeks of initial treatment (32 weeks total). In one study, patients were assigned randomly to placebo or to the same dose of citalopram (20 to 60 mg/day) during maintenance treatment as they had received during the acute stabilization phase, while in the other study, patients were assigned randomly to continuation of citalopram 20 or 40 mg/day, or placebo, for maintenance treatment. In the latter study, the rates of relapse to depression were similar for the two dose groups (see CLINICAL TRIALS under CLINICAL PHARMACOLOGY). Based on these limited data, it is not known whether the dose of citalopram needed to maintain euthymia is identical to the dose needed to induce remission. If adverse reactions are bothersome, a decrease in dose to 20 mg/day can be considered.

Discontinuation of Treatment with Citalopram

Symptoms associated with discontinuation of citalopram and other SSRIs and SNRIs have been reported (see PRECAUTIONS). Patients should be monitored for these symptoms when discontinuing treatment. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Switching a Patient To or From a Monoamine Oxidase Inhibitor (MAOI) Intended to Treat Psychiatric Disorders

At least 14 days should elapse between discontinuation of an MAOI intended to treat psychiatric disorders and initiation of therapy with citalopram. Conversely, at least 14 days should be allowed after stopping citalopram before starting an MAOI intended to treat psychiatric disorders (see CONTRAINDICATIONS).

Use of citalopram with Other MAOIs, Such as Linezolid or Methylene Blue

Do not start citalopram in a patient who is being treated with linezolid or intravenous methylene blue because there is an increased risk of serotonin syndrome. In a patient who requires more urgent treatment of a psychiatric condition, other interventions, including hospitalization, should be considered (see CONTRAINDICATIONS) .

In some cases, a patient already receiving citalopram therapy may require urgent treatment with linezolid or intravenous methylene blue. If acceptable alternatives to linezolid or intravenous methylene blue treatment are not available and the potential benefits of linezolid or intravenous methylene blue treatment are judged to outweigh the risks of serotonin syndrome in a particular patient, citalopram should be stopped promptly, and linezolid or intravenous methylene blue can be administered. The patient should be monitored for symptoms of serotonin syndrome for 2 weeks or until 24 hours after the last dose of linezolid or intravenous methylene blue, whichever comes first. Therapy with citalopram may be resumed 24 hours after the last dose of linezolid or intravenous methylene blue (see WARNINGS).

The risk of administering methylene blue by non-intravenous routes (such as oral tablets or by local injection) or in intravenous doses much lower than 1 mg/kg with citalopram is unclear. The clinician should, nevertheless, be aware of the possibility of emergent symptoms of serotonin syndrome with such use (see WARNINGS).

Indications and Usage Section

INDICATIONS AND USAGE

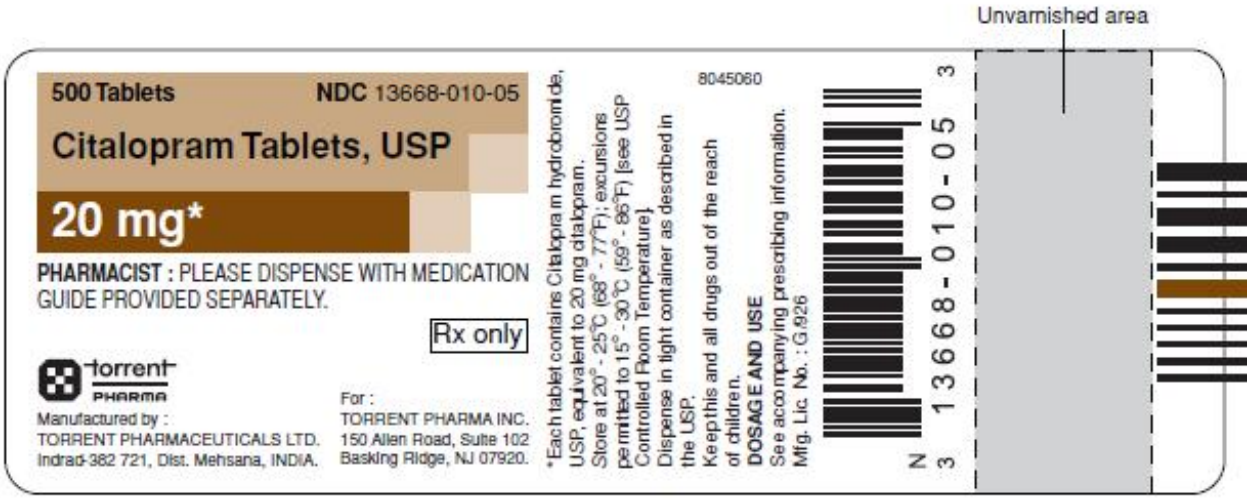
Citalopram, is indicated for the treatment of depression.

The efficacy of citalopram hydrobromide, in the treatment of depression was established in 4 to 6 week, controlled trials of outpatients whose diagnosis corresponded most closely to the DSM-III and DSM-III-R category of major depressive disorder (see CLINICAL PHARMACOLOGY).

A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, a suicide attempt or suicidal ideation. The antidepressant action of citalopram in hospitalized depressed patients has not been adequately studied.

The efficacy of citalopram in maintaining an antidepressant response for up to 24 weeks following 6 to 8 weeks of acute treatment was demonstrated in two placebo-controlled trials (see CLINICAL PHARMACOLOGY). Nevertheless, the physician who elects to use citalopram for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Principal Display Panel



CELEXA

citalopram hydrobromide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0093(NDC:13668-010)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CITALOPRAM HYDROBROMIDE (UNII: I1E9D14F36) (CITALOPRAM - UNII:0DHU5B8D6V)	CITALOPRAM	20 mg

Product Characteristics			
Color	brown	**Score**	2 pieces
Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	2;0;1010
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80425-0093-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/18/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078216	10/18/2007	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0093)