Citalopram is an antidepressant drug used to treat major depression associated with mood disorders. It is also used on occasion in the treatment of body dysmorphic disorder and anxiety.



HBr

Active Pharmaceuticals Ingredients Manufacturers

# Taj Pharmaceuticals Ltd. Citalopram Hbr CAS No. : 59729-32-7

Citalopram hydrobromide Synonyms 1-[3-(Dimethylamino)propyl]-1-(4-fluorophenyl)-1, 3-dihydro-5-isobenzofurancarbonitrile hydrobromide

CAS Registry Number 59729-32-7

## Molecular Formula

C20H21FN2O.HBr;C20H22BrFN2O Molecular Weight 405.31 EINECS 261-890-6 Melting point 182-188 °C

#### **Chemical data**

Formula C20H21FN2O Mol. mass 324.392 g/mol Pharmacokinetic data Bioavailability 80% Metabolism hepatic (CYP3A4 & CYP2C19) Half life 35 hours Excretion Mostly as unmetabolized Citalopram, partly DCT and traces of DDCT in urine

## DOSAGE

The usual starting dose is 20 mg in the morning or evening. The dose may be increased to 40 mg daily after one week. A dose of 60 mg has not been shown to be more effective than 40 mg. As with all antidepressants, it may take several weeks of treatment before maximum effects are seen. Doses are often slowly adjusted upwards to find the most effective dose.

Citalopram comes as a tablet and a solution (liquid) to take by mouth. It is usually taken once a day with or without food. Take citalopram at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take citalopram exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor may start you on a low dose of citalopram and gradually increase your dose, not more often than once a week.

It may take 1 to 4 weeks before you feel the full benefit of citalopram. Continue to take citalopram even if you feel well. If you suddenly stop taking citalopram, you may experience withdrawal symptoms such as mood changes, irritability, agitation, dizziness, numbness or tingling in the hands or feet, anxiety, confusion, headache, tiredness, and difficulty falling asleep or staying asleep. Do not stop taking citalopram without talking to your doctor. Your doctor will probably decrease your dose gradually.top link

# SIDE EFFECTS

Citalopram may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- \* nausea
- \* diarrhea



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Taj Pharmaceuticals Ltd. Citalopram

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- \* vomiting
- \* stomach pain
- \* drowsiness
- \* excessive tiredness
- \* uncontrollable shaking of a part of the body
- \* excitement
- \* nervousness
- \* muscle or joint pain
- \* dry mouth
- \* excessive sweating
- \* changes in sex drive or ability
- \* loss of appetite

The most common side effects associated with citalopram are nausea, dry mouth, vomiting, excessive sweating, headache, tremor, drowsiness, and inability to sleep. Overall,



between 1 in 6 and 1 in 5 persons experience a side effect. Citalopram is also associated with sexual dysfunction. Some patients may experience withdrawal reactions upon stopping citalopram. Symptoms of withdrawal include dizziness, tingling sensations, tiredness, vivid dreams, and irritability or poor mood.

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with depression and other psychiatric disorders. Anyone considering the use of citalopram or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be closely observed for clinical worsening, suicidality, or unusual changes in behavior.

# PRECAUTIONS

Do not use citalopram if you are using an MAO inhibitor such as isocarboxazid (Marplan), tranylcypromine (Parnate), phenelzine (Nardil), rasagiline (Azilect), or selegiline (Eldepryl, Emsam). Serious and sometimes fatal reactions can occur when these medicines are taken with citalopram. You must wait at least 14 days after stopping an MAO inhibitor before you can take citalopram. After you stop taking this medication, you must wait at least 14 days before you start taking an MAOI.

Before taking citalopram, tell your doctor if you are allergic to any drugs, or if you have:

\* liver or kidney disease;

\*seizures or epilepsy;

\*bipolar disorder (manic depression); or

\*a history of drug abuse or suicidal thoughts.

If you have any of these conditions, you may need a dose adjustment or special tests to safely take citalopram.

You may have thoughts about suicide when you first start taking an antidepressant, especially if you are younger than 24 years old. Tell your doctor if you have worsening symptoms of depression or suicidal thoughts during the first several weeks of treatment, or whenever your dose is changed.

Your family or other caregivers should also be alert to changes in your mood or symptoms. Your doctor will need to check you at regular visits for at least the first 12 weeks of treatment with citalopram.



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#### DRUG DESCRIPTION

Citalopram is an antidepressant drug used to treat major depression associated with mood disorders. It is also used on occasion in the treatment of body dysmorphic disorder and anxiety.

Citalopram belongs to a class of drugs known as selective serotonin reuptake inhibitors (SSRIs).

It works by increasing the amount of serotonin, a natural substance in the brain that helps maintain mental balance.top link

Citalopram is an antidepressant medication that affects neurotransmitters, the chemicals that nerves within the brain use to communicate with each other. Neurotransmitters are manufactured and released by nerves and then travel and attach to nearby nerves. Thus, neurotransmitters can be thought of as the communication system of the brain. Many experts believe that an imbalance among neurotransmitters is the cause of depression. Citalopram works by preventing the uptake of one neurotransmitter, serotonin, by nerve cells after it has been released. Since uptake is an important mechanism for removing released neurotransmitters and terminating their actions on adjacent nerves, the reduced uptake caused by citalopram results in more free serotonin in the brain to stimulate nerve cells.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at: http://www.tajapi.com or by contacting the sponsor, Taj Pharmaceuticals Limited., at: 91 022 30601000. This leaflet was prepared by Taj Pharmaceuticals Limited, Mumbai (India). MPSTJ278 Last revised: 29 August 2009



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