

APO-CITALOPRAM TABLET

Citalopram Hydrobromide (20mg)

What is in this leaflet

1. What Apo-Citalopram is used for
2. How Apo-Citalopram works
3. Before you use Apo-Citalopram
4. How to use Apo-Citalopram
5. While you are using it
6. Side effects
7. Storage and Disposal of Apo-Citalopram
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Apo-Citalopram is used for

APO-CITALOPRAM is a prescription medication containing the active ingredient, citalopram hydrobromide. APO-CITALOPRAM is intended for the relief of symptoms of depression and to prevent any relapse or reoccurrence.

Treatment with these types of medications is most safe and effective when you and your doctor have good communication about how you are feeling.

This medication can also be used for panic disorder with or without agoraphobia (fear of social environment or situation) and Obsessive Compulsive Disorder (OCD) as well.

How Apo-Citalopram works

APO-CITALOPRAM is a form of selective serotonin reuptake inhibitor (SSRI). It works by increasing the amounts of certain natural substances in the brain that are needed to maintain mental balance.

Before you use Apo-Citalopram

- When you must not use it

If you are allergic to any citalopram products, or if you are

on a treatment with monoamine oxidase inhibitor (MAOI).

- Before you start to use it

Before taking APO-CITALOPRAM your doctor needs to know:

- Any other medical condition that you may have including heart diseases, seizures;
- Any known history of mania, or hypomania.
- Whether you are planning to get pregnant, are currently pregnant or are nursing an infant;
- Any history of drug abuse or suicidal thoughts;
- Presence of any bleeding or blood clotting disorder
- If you are a diabetic patient

- Taking other medicines

Let your doctor know if you are taking any other prescription or over-the-counter medication. Citalopram should not be used in combination with the following:

- Monoamine oxidase inhibitor (MAOI). Citalopram may be started 14 days after discontinuing treatment with an irreversible MAOI and at least one day after discontinuing treatment with the reversible MAOI (RIMA), moclobemide.

At least 7 days should elapse after discontinuing citalopram treatment before starting a MAOI or RIMA.

- Drug known to affect platelet function such as atypical antipsychotics and phenothiazines, tricyclic antidepressants, aspirin and non-steroidal anti-inflammatory drugs (NSAIDs).

- Metoprolol (an agent to lower high blood pressure)

- Cimetidine (to treat stomach disorder)

How to use Apo-Citalopram

- How much to use **Antidepressant:**

APO-CITALOPRAM should be administered as a single oral dose of 20mg daily.

Establishing an effective dosage level will vary from one person to another. For this reason, your doctor may increase your dosage gradually, up to 60mg daily during treatment. It is very important that you take APO-CITALOPRAM exactly as your doctor has instructed.

Panic disorder:

Initial dose for panic disorder should be 10mg daily and increased gradually, up to 60mg daily according to the patient's requirement.

If the condition is not suppressed after 3 months of treatment, consult your doctor as you may require a prolonged treatment period.

Obsessive Compulsive Disorder:

For adults, the initial dose should be 20mg, and increased gradually up to 60mg daily.

For elderly patients, the recommended dose is 20mg, and increased to max 40mg daily.

Children are not recommended to take this medication as the safety and efficacy have not been established for this age population.

- When to use it

APO-CITALOPRAM should be taken according to the doctor's instructions or the label attached with this medication. Swallow the tablet(s) with water and without chewing.

- How long to use it

Never increase or decrease the amount of APO-CITALOPRAM you, or those in your care if you are a caregiver or guardian, are taking unless your doctor tells you to and do not stop taking this medication without consulting your doctor.

- If you forget to use it

As soon as you remember, take the missed dose. Unless if it is almost time for your next scheduled dose, skip the missed dose. Do not take extra medicine to make up the missed dose.

- If you use too much (overdose)

Contact your doctor or nearest hospital emergency department even though you may not feel sick.

Symptoms of overdose might include somnolence (sleepiness), coma, stiffened expression, episode of grand mal convulsion (generalised seizure), sinus tachycardia (faster than normal heart rate), occasional nodal rhythm (heart rhythm), sweating, nausea, vomiting, cyanosis (abnormal blue discoloration of the skin), hyperventilation

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Apo-Citalopram*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Apo-Citalopram* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

This medication might cause suicidality in children and adolescents. Antidepressant increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorder.

Families and caregivers should be advised to closely observe the patient and to communicate with the prescriber. This product is not indicated for paediatric use.

Refrain from potentially hazardous tasks, such as driving a car or operating dangerous machines, until you are certain that this medication does not affect your mental alertness or physical coordination.

If you are pregnant and taking citalopram, or other antidepressants, you should discuss the risks and benefits of the various treatment options with your doctor.

It is very important that you do NOT stop taking these medications without first consulting your doctor.

Side effects

The side effects of taking Citalopram are usually mild and transient. These side effects are most strongly experienced during the first two weeks of the initiation of the treatment.

The side effects include nausea, drowsiness, dry mouth, increased sweating and tremor. However, if you feel any other forms of

discomfort when you take the medication, let your doctor know as soon as possible.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drugs Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting)

Storage and Disposal of Apo-Citalopram

- Storage

Remember to keep APO-CITALOPRAM and all medications safely away from children.

Do not use this medicine after the month and year written after EXP on the container.

Store APO-CITALOPRAM at below 25°C.

- Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

The 20mg tablets are white, oval, biconvex, film-coated tablet. Scored and engraved 20 on one side, APO on the other side

- Ingredients

- Active ingredient: Citalopram Hydrobromide

- Inactive ingredients : Lactose Monohydrate(Spray dried) NF, Microcrystalline Cellulose (PH

102) NF, Croscarmellose Sodium
NF, Magnesium Stearate NF,
Hydroxyethyl Cellulose (Type
250 L), NF, Polyethylene Glycol
8000, Titanium Dioxide and
Purified Water.

- MAL Number:

Apo-Citalopram 20mg tab
(MAL08061582A)

Manufacturer

Apotex Inc – Etobicoke Site
50 Steinway Boulevard
Etobicoke, Ontario
Canada M9W 6Y3

Product Registration Holder

Pharmaforte (M) Sdn Bhd
2, Jalan PJU 3/49
Sunway Damansara
47810 Petaling Jaya

Date of revision

8/1/2015

Serial number

BPFK(R4/1)241214/00086