

APO-FLUVOXAMINE

Fluvoxamine maleate (50mg, 100mg)

What is in this leaflet

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

What Apo-Fluvoxamine is used for

Apo-Fluvoxamine is intended for the relief of symptoms of depression, or the reduction of symptoms associated with obsessive-compulsive disorder (OCD; persistent, obsessive thoughts that make you carry out repetitive behaviour).

How Apo-Fluvoxamine works

Apo-Fluvoxamine contains the active ingredient fluvoxamine. Apo-Fluvoxamine belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs) antidepressants.

Apo-Fluvoxamine is believed to work by enhancing the availability of serotonin, one of the chemical substances in the brain. Depression and OCD have been associated with a decrease in the flow of serotonin between certain brain cells.

Before you use Apo-Fluvoxamine

- When you must not use it

Do not use this product if you are allergic to fluvoxamine maleate, or any other ingredients in this medication. (See product description)

Do not take Apo-Fluvoxamine if you are taking or have recently taken medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide) within the last 14 days. Check with your doctor or pharmacist if you are unsure as to whether or not you are taking MAOI.

- Before you start to use it

Before taking Apo-Fluvoxamine your doctor needs to know any other medical condition that you may have including :

- a history of seizures
- liver problems
- kidney problems
- heart problems or have had a recent heart attack
- diabetes
- a history of bleeding disorders
- a history of suicide-related events
- a history of mania (uncontrollable excitement that causes over-activity)/hypomania (a condition similar to mania but less severe).
- electroconvulsive therapy (ECT), for severe depression or other mental illnesses

Pregnancy and lactation

Tell your doctor if you are pregnant, think you might be pregnant now, are planning to become pregnant or if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine. Do not take Apo-Fluvoxamine until you and your doctor have discussed the risks and benefits involved.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Apo-fluvoxamine. These include:

- MAOIs (see When you must not use it.)
- Other medicines for depression, such as tricyclic antidepressants (TCAs) or other SSRIs
- Medicines used to relieve anxiety, such as alprazolam

- Blood thinning medicines, such as warfarin
- Medicines used to treat mental illness, such as lithium
- Medicines to control fits, such as phenytoin and carbamazepine
- Medicines used to relieve anxiety, such as alprazolam and diazepam
- Medicines used to treat heart conditions, such as digoxin

How to use Apo-Fluvoxamine

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Depression

Adults: The recommended dose is 100 mg daily. The initial dose should start at 50 or 100 mg, given as a single dose in the evening.

Children/adolescents: Fluvoxamine should not be used in children and adolescents under the age of 18 years for the treatment of major depressive episode. The efficacy and safety of Fluvoxamine have not been established in the treatment of pediatric major depressive episode.

Obsessive Compulsive Disorder

Adults: The recommended dose is between 100-300 mg daily. The initial dose should start at 50 mg per day.

Children/adolescents: The maximum dose in children should not exceed 200 mg/day. It is advisable that a total daily dose of more than 50 mg should be given in two divided doses. If the two divided doses are not equal, the larger dose should be given at bedtime.

The above is just the recommended dose. Your doctor will monitor your condition and might adjust your dosage to suit your ability to cope with this medication.

- When to use it

Use as directed by your doctor or pharmacist.

Take the Apo-Fluvoxamine tablet by mouth, preferably in the evening.

- How long to use it

Continue taking Apo-Fluvoxamine for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms include gastro-intestinal complaints (nausea, vomiting and diarrhea), somnolence and dizziness. Abnormal heart activities, liver function disturbances, convulsions (fits) and coma have also been reported.

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-Fluvoxamine.

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.

Your doctor may want you to gradually reduce the amount of Apo-fluvoxamine you are taking before stopping completely. This should help reduce the chance of withdrawal symptoms (such as dizziness, paresthesia [tingling sensation], headache, nausea and anxiety)

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Suicidality in Children and Adolescent

Apo-Fluvoxamine increases the risk of suicidal ideation and behavior in children. Despite this, your doctor may prescribe Apo-Fluvoxamine for you or your child when he/she decides that this is in their best interests.

If your doctor has prescribed Apo-Fluvoxamine for a child under 18 and you want to discuss this, please go back to your doctor. Families or caregivers should pay close attention to your child whenever Apo-Fluvoxamine is started or its dose is changed. Contact your doctor if you notice any sudden or unusual changes in you or your child's behavior.

Side effects

Like all medicines, Apo-Fluvoxamine can cause side effects, although not everybody gets them.

Common side effects might include nausea, constipation, diarrhea, upset

stomach, dizziness, or headache.

If you experience the following rare, but very serious side effect, stop taking Apo-Fluvoxamine and tell your doctor immediately or contact the casualty department at your nearest hospital:

- allergic reaction including skin rash, swelling of the face, lips, tongue or throat, difficulty breathing
- thoughts of suicide or attempting suicide or self-harm
- serotonin syndrome including rapid heart beat, sweating, restlessness, tremors, convulsions (fits), confusions and hallucination (hearing voices or seeing things which are not there)

Other side effects not listed above may also occur in some people.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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

Storage and Disposal of Apo-Fluvoxamine

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

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 50 mg tablets are round, white, biconvex, film-coated, engraved "APO" on one side, scored and engraved "50" on the other.

The 100 mg tablets are oval, white, biconvex, film-coated, scored and engraved "APO 100" on one side, other side plain.

- Ingredients

- Active ingredient
Fluvoxamine maleate

- Inactive ingredients
50mg & 100mg: Magnesium stearate, mannitol, hydroxypropyl methylcellulose, polydextrose, polyethylene glycol, titanium dioxide and carnauba wax.

- MAL numbers:

Apo-Fluvoxamine 50mg tab
(MAL06091399AZ)

Apo-Fluvoxamine 100mg tab
(MAL07061425AZ)

Manufacturer

Apotex Inc.
150 Signet Drive
Weston Toronto Ontario
M9L 1T9 Canada

Product Registration Holder

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

Date of revision

11/11/2015

Serial Number

BPFK(R4/1)161015/00366