

APO-Fluvoxamine Tablets

Contains the active ingredient fluvoxamine (as fluvoxamine maleate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about fluvoxamine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Fluvoxamine. It contains the active ingredient maleate.

It is used to treat:

- Depression in adults
- Obsessive compulsive disorder (OCD) in adults, adolescents and children eight years old and above.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Fluvoxamine belongs to a family of medicines known as selective serotonin reuptake inhibitors (SSRIs).

Depression

Fluvoxamine is used to treat depression in adults only. It is not recommended for treatment of this condition in children and adolescents as the safety and effectiveness of this medicine, when used for depression in this age group, have not been established.

Depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life.

It can affect your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty for no reason.

Obsessive compulsive disorder (OCD)

Fluvoxamine is also used to treat a condition known as obsessive compulsive disorder (OCD) in adults and children eight years of age or older.

People with OCD can have two types of symptoms - obsessions and compulsions.

Obsessions are unwanted repeated thoughts or feelings, which are ongoing.

Compulsions are the need to repeat actions over and over. The symptoms of OCD can vary from patient to patient.

Both of these conditions are thought to be caused by a chemical imbalance in parts of the brain.

Fluvoxamine corrects this chemical imbalance and may help relieve the symptoms of depression and OCD.

There is no evidence that this medicine is addictive.

Use in children

Depression

There is not enough information to recommend the use of this medicine for treating depression in children and adolescents (under 18 years of age).

OCD

There is not enough information to recommend the use of this medicine for treating OCD in children under eight years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if you are taking another anti-depressant medicine called a monoamine oxidase inhibitor (MAOI).

Do not take fluvoxamine until 14 days after stopping any irreversible MAOI, and do not take any MAOIs until more than one week after stopping fluvoxamine.

Taking fluvoxamine with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Ask your doctor or pharmacist if you are not sure if you have been taking any of these medicines.

Do not take this medicine if you are taking a medicine called cisapride, used for treating stomach problems.

Do not take this medicine if you are taking a medicine called tizanidine, used for treating the symptoms of multiple sclerosis or spinal cord injury.

Do not take this medicine if you are taking a medicine called linezolid, an antibiotic.

Do not take this medicine if you have or have had any of the following:

- **You are breastfeeding.**
Fluvoxamine may pass into human breast milk.

- **You have had an allergic reaction to fluvoxamine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver problems
 - kidney problems
 - bipolar disorder
 - epilepsy or fits
 - eye disorders such as high pressure in your eye or those at risk of glaucoma
 - bleeding problems
 - other blood disorders, including thrombocytopenia
 - diabetes
 - thoughts or actions relating to self-harm or suicide.
3. You are currently pregnant or you plan to become pregnant.
There have been reports that babies exposed to fluvoxamine and other antidepressants during the third trimester of pregnancy may develop complications after birth. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed.
Like many other medicines, it can pass into breast milk and may affect your baby. Do not take this medicine whilst breastfeeding.
5. You drink alcohol.
Your doctor may suggest avoiding alcohol while you are being treated for depression.
6. You are planning to have surgery or an anaesthetic or any medical tests or treatments.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some combinations of medicines may increase the risk of serious side effects and are potentially life-threatening.

These medicines must not be taken with fluvoxamine. They include:

- MAOIs

- tizanidine
- cisapride

(See also "When you must not take it").

Some medicines may interact with fluvoxamine. These include:

- other medicines used to treat depression or obsessive compulsive disorder, such as amitriptyline, imipramine, clomipramine, fluoxetine, citalopram, sertraline, paroxetine)
- diazepam, alprazolam, triazolam and midazolam, drugs called benzodiazepines which are used for sleeping and anxiety
- medicines used to treat certain mental and emotional conditions, called antipsychotics (e.g. haloperidol, thioridazine, olanzapine, quetiapine and clozapine)
- medicines (tablets or injections) used for diabetes
- aspirin and medicines for arthritis and inflammation (non-steroidal anti-inflammatory drugs - NSAIDs)
- medicines used to thin the blood, such as warfarin
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to control fits, such as carbamazepine and phenytoin
- sumatriptan, and other medicines called triptans used to treat migraines
- tramadol, a strong pain-killer
- phentermine, a weight loss medicine
- tacrine, used for treating Alzheimer's Disease
- theophylline, used to help breathing problems
- methadone, a medicine used to treat drug addiction
- mexiletine, used to treat heart problems
- propranolol which lowers blood pressure or treats heart conditions
- St John's Wort (*Hypericum perforatum*) or tryptophan, contained in some multivitamin and herbal preparations, which can be bought without a prescription
- cyclosporine, used in organ transplants, psoriasis, arthritis and other conditions.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with fluvoxamine.

If you smoke the levels of fluvoxamine in your blood may be lower.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

To treat depression:

Adults: The usual starting dose is 50 mg each day, usually in the evening but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved.

To treat OCD:

Adults: The usual starting dose is 50 mg each day, usually in the evening, but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved.

Children & Adolescents (8 to 17 years): The usual starting dose is 25 mg each day, usually at bedtime. The doctor will probably adjust the dose until the desired response is achieved.

If you are elderly and/or have liver or kidney problems your doctor may adjust the dose more slowly.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablet with a full glass of water. Do not chew the tablets.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

The length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so don't be discouraged if you don't feel better right away.

Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take your tablets for several months or even longer to make sure the benefits are maintained.

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.

Also contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

This medicine should not be stopped abruptly, especially if you are taking 200 mg or more per day.

If your doctor decides that you should stop treatment, then the dose should be reduced by 100 mg every three days.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The most common symptoms are nausea (feeling sick), vomiting and diarrhoea. You could also experience drowsiness and dizziness, or feel faint. There have been cases of irregular heartbeat, fits and coma.

While you are taking this medicine

Things you must do

People taking fluvoxamine may be more likely to think about killing themselves or actually try to do so, especially when fluvoxamine is first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using fluvoxamine who talks about or shows signs of killing him or herself.

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse during the first one to two months of taking fluvoxamine until the medicine starts to work completely. This is more likely to occur if you are a young adult, i.e. 18 to 24 years of age, and you have not used antidepressant medicines before.

If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking fluvoxamine, contact a doctor immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts of talk of self-harm or harm to others
- any recent attempts of suicide or self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant (tell your doctor immediately). When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like fluvoxamine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests

- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

If you are under 18 years of age your doctor will monitor your weight and growth carefully.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

This will help your doctor to determine the best treatment for you.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

It may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

Although drinking moderate amounts of alcohol is unlikely to affect your response to fluvoxamine, your doctor may suggest avoiding alcohol while you are being treated for depression.

You should minimise your intake of caffeine-containing beverages (e.g. coffee, tea) while taking this product.

Large amounts of caffeine may result in side effects such as tremor (shaking), palpitations (fast or irregular heart beat), nausea, restlessness and trouble or inability to sleep.

Older people may become confused when taking this medicine. Families and carers should be aware of this. Special care may be needed.

You should be careful for 1 or 2 weeks after stopping this medicine, because it will still be in your blood stream.

You should be aware that people over 50 years of age who take antidepressants have an increased risk of having a bone fracture.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking fluvoxamine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- nausea, vomiting, dry mouth, stomach pain, constipation, diarrhoea, heart burn, loss of appetite, abnormal taste, weight gain, weight loss
- drowsiness, difficulty sleeping, dizziness, nervousness, feeling anxious or agitated, headache
- muscle or general body weakness, pins and needles, shaking
- muscle or joint pain
- dilated (larger) pupil of the eye

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention.

- muscle spasms or twitches
- sensitivity of the skin to sunlight
- excessive bleeding or dark stools (may indicate a gut bleed)
- feeling dizzy or faint after standing up quickly
- sexual problems
- inappropriate milk secretion
- feeling confused, uncoordinated or making unintended movements, having an unusual posture
- restlessness, urge to move, pacing, swinging legs while seated, rocking from foot to foot
- hearing, seeing or feeling things that are not there
- problems with your liver, shown by yellow skin or eyes, or pale stools
- faster or thumping heart beat, sweating, or unusual bruising.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation.

- Mood of excitement, over-activity and uninhibited behaviour (a manic episode)
- Sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body
- Sudden increase in body temperature, severe convulsions (fits)
- Fast heartbeat, sweating, racing thoughts and restlessness.

Other side effects observe more frequently in children are: abnormal thoughts or behaviour, cough, increased period pain, nose bleeds, increased restlessness, infection and sinusitis.

Tell your doctor if you notice anything else that is making you feel unwell including any suicidal thoughts or other mental/mood changes (see "Things you must do").

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to fluvoxamine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing

- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Fluvoxamine looks like

- **Fluvoxamine 50 mg tablets**
Golden, round, scored tablet, film-coated, engraved "APO" on one side, "F" over bisect "50" on the other side.
Packs of 30 tablets in blisters.
- **Fluvoxamine 100 mg tablets**
Reddish-brown, pillow-shaped scored tablet, film-coated, engraved "APO" on one side and "FLU bisect 100" on the other side.
Packs of 30 tablets in blisters.

Not all strengths may be available.

Ingredients

Each tablet contains 50 mg or 100 mg of fluvoxamine maleate as the active ingredient.

It also contains the following inactive ingredients:

- magnesium stearate
- mannitol
- hydroxyethyl cellulose
- macrogol 8000
- titanium dioxide
- iron oxide yellow
- iron oxide red (100 mg tablets only)
- iron oxide black (100 mg tablets only)

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

- **APO-Fluvoxamine 50 mg tablets:**
AUST R 147380
- **APO-Fluvoxamine 100 mg tablets:**
AUST R 147389

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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