

# **APO-Fluvoxamine**

Fluvoxamine maleate

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## **Consumer Medicine Information**

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

## **What is in this leaflet**

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.

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.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may want to read it again.

## **What this medicine is used for**

Fluvoxamine is used to treat depression in adults, as well as obsessive compulsive disorder (OCD) in adults and children aged eight years old and above.

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

It works to correct the chemical imbalance in the brain that are thought to cause depression and OCD, helping to relieve symptoms.

### **Depression**

Depression can cause emotional and physical symptoms such as loss of interest in activities, disturbed sleep and lack of energy.

### **OCD**

Patients with OCD can have two types of symptoms – obsessions (unwanted repeated thoughts or feelings) and compulsions (the need to repeat actions over and over).

**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.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for treating depression in children aged under 18 years, or 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 have an allergy to:**

- fluvoxamine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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

**Do not take fluvoxamine with a monoamine oxidase inhibitor (MAOI), or until 14 days after stopping any irreversible MAOI. Do not take any MAOIs until more than one week has passed after stopping fluvoxamine.**

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

**Do not take this medicine if you are taking the following medicines:**

- cisapride, used for stomach problems
- tizanidine, used for the symptoms of spinal cord problems
- linezolid, an antibiotic
- ramelteon, used to help you sleep

**Do not take this medicine if you are breastfeeding.**

Fluvoxamine can pass into human breast milk and may affect your baby.

**Do not take this medicine after the expiry date printed on the pack, the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

**Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- liver or kidney problems
- bipolar disorder, mania or any other mental illness
- epilepsy or fits
- eye disorders such as high pressure in your eye or glaucoma
- bleeding problems
- other blood disorders, including thrombocytopenia
- low levels of sodium in your blood
- diabetes
- thoughts or actions relating to self-harm or suicide

**Tell your doctor if you are pregnant or 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 or if you are planning to become pregnant until you and your doctor have discussed the risks and benefits involved.**

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

## **Taking other medicines**

**Tell your doctor if you are taking any other medicines, including any that you get 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:**

- monoamine oxidase inhibitors (MAOIs) e.g. moclobemide and selegiline
- tizanidine
- cisapride
- ramelteon

Some medicines may interact with fluvoxamine. These include:

- other medicines used to treat depression or OCD (e.g. amitriptyline, imipramine, clomipramine, fluoxetine, citalopram, sertraline or paroxetine)
- benzodiazepines used for anxiety (e.g. diazepam, alprazolam, triazolam or midazolam)

- antipsychotic medicines used to treat schizophrenia (e.g. haloperidol, thioridazine, olanzapine, quetiapine or clozapine)
- medicines used for diabetes (tablets or injections)
- aspirin and medicines for arthritis and inflammation (e.g. non-steroidal anti-inflammatory drugs- (NSAIDs))
- medicines used to thin the blood (e.g. warfarin or clopidogrel)
- lithium, used for mood disorders
- medicines used to control fits, (e.g. carbamazepine or phenytoin)
- medicines used to treat migraines such as sumatriptan, zolmitriptan or eletriptan (triptans) or some strong pain-killers (e.g. tramadol, methadone)
- phentermine, a weight loss medicine
- tacrine, used for Alzheimer's Disease
- theophylline, used to help breathing problems
- some medicines used to treat heart problems (e.g. mexiletine or propranolol)
- St John's Wort (*Hypericum perforatum*) or tryptophan, contained in some herbal preparations
- cyclosporin, used to suppress the immune system

- terfenadine or astemizole, used for allergies
- sildenafil, used for erectile dysfunction

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.**

They may differ to the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

## **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. Your doctor may adjust your dose until the desired response is achieved.

### **Depression:**

The usual starting dose is 50mg each day, usually in the evening.

## **OCD:**

Adults: The usual starting dose is 50mg each day, usually in the evening.

Children (8 to 17 years): The usual starting dose is 25mg each day, usually at bedtime.

## **How to take it**

**Swallow the tablet whole with a 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. It will also help you remember when to take it.

It does not matter if you take it with or without food.

## **How long to take it for**

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

The length of treatment will depend on how quickly your symptoms improve. 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.

**This medicine should not be stopped abruptly unless your doctor advises you to do so.**

If your fluvoxamine treatment needs to be stopped, your doctor or pharmacist will provide you with instructions to reduce the dose gradually over a period of at least one or two weeks.

### **If you forget to take it**

**If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.**

**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 the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

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

### **If you take too much (overdose)**

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go**

**to Accident and Emergency at your nearest hospital if you think that 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.**

If you take too much fluvoxamine, you might experience the following symptoms:

- nausea or vomiting
- diarrhoea
- drowsiness, dizziness, faintness

You could also experience 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 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 themselves.**

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

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**

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

**If you become pregnant while taking fluvoxamine, tell your doctor immediately.**

When taken during pregnancy, particularly in the last 3 months, 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 doctor immediately.

**Tell your doctor you are taking fluvoxamine if you are about to have any blood tests, going into surgery or a hospital.**

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

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.

## **Things you must not do**

**Do not give this medicine to anyone else, even if they have the same condition as you.**

**Do not take your medicine to treat any other complaint unless your doctor tells you to.**

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

## **Things to be careful of**

**Be careful 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.

**You should avoid alcohol while you are being treated with fluvoxamine.**

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

Large amounts of caffeine may result in side effects such as tremor, fast or irregular heartbeat, nausea, restlessness, or trouble sleeping.

Older people may become confused when taking this medicine. Special care may be needed. Also, people over 50

years of age who take antidepressants have an increased risk of having a bone fracture.

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

## **Side effects**

**Tell your doctor and pharmacist as soon as possible if you do not feel well while you are taking fluvoxamine.**

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following:**

- nausea or vomiting,
- dry mouth
- stomach pain, constipation or diarrhoea
- heart burn, loss of appetite or abnormal taste

- weight gain or weight loss
- drowsiness or difficulty sleeping
- dizziness, nervousness, feeling anxious or agitated
- headache
- muscle or general body weakness, pins and needles or 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:**

- muscle spasms or twitches
- sensitivity of the skin to sunlight
- excessive bleeding or dark stools (signs of bleeding from the gut)
- feeling dizzy or faint after standing up quickly
- sexual problems
- inappropriate milk secretion
- feeling confused, uncoordinated or making unintended movements or unusual posture

- restlessness, urge to move, pacing, swinging legs while seated or rocking from foot to foot
- hearing, seeing or feeling things that are not there
- yellow skin or eyes, or pale stools (signs of liver problems)
- fast or thumping heartbeat, sweating, or unusual bruising

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

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- excitement, over-activity and uninhibited behaviour (possible signs of a manic episode)
- sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body
- sudden increase in body temperature or convulsions (fits)
- fast heartbeat, sweating, racing thoughts and restlessness
- severe skin reaction with painful red areas, large blisters and peeling skin – this may be accompanied by fever and chills, aching muscles and generally feeling unwell
- symptoms of an allergic reaction including 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

The above list includes very serious side effects and you may need urgent medical attention or hospitalisation.

**Other side effects observed more frequently in children are:**

- abnormal thoughts or behaviour
- cough
- increased period pain
- nose bleeds or sinusitis
- increased restlessness
- infection

**Tell your doctor if you notice anything else that is making you feel unwell, or if you experience any suicidal thoughts or mood changes.**

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

# **Storage and disposal**

## **Storage**

**Keep your medicine in its pack until it is time to take it.**

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

**Keep your medicine in a cool dry place where the temperature stays 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 the expiry date has passed, ask your pharmacist what to do with any medicine left over.**

## **Product description**

### **What it looks like**

**50mg tablets**

Golden, round, scored tablet, film-coated, engraved "APO" on one side, "F" over bisect "50" on the other side. AUST R 147380.

### **100 mg tablets**

Reddish-brown, pillow-shaped scored tablet, film-coated, engraved "APO" on one side and "FLU bisect 100" on the other side. AUST R 147389.

Available in 30 tablets in blister packs.

\*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:

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

- iron oxide black (100 mg tablets only)

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

## **Sponsor**

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