

FLUVOXIN 50MG FILM COATED TABLETS

FLUVOXIN 100MG FILM COATED TABLETS

Fluvoxamine maleate (50mg, 100mg)

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What **FLUVOXIN** is used for

It is used to treat depression. **FLUVOXIN** can also treat people who have obsessive compulsive disorder (OCD).

How **FLUVOXIN** works

FLUVOXIN belongs to a group of medicines called selective serotonin re-uptake inhibitors (SSRI). It contains a substance called fluvoxamine that works to correct the chemical imbalance in the brain that are thought to cause depression and OCD, helping to relieve symptoms.

Before you use **FLUVOXIN**

- When you must not use it

- If you are allergic to fluvoxamine maleate or any of the ingredients listed at the end of this leaflet
- You are taking medicines called monoamine oxidase inhibitors (MAOI) or have taken them in the last two weeks. Your doctor will advise you how you should begin taking **FLUVOXIN** once you have stopped taking the MAOI. This medicine is sometimes prescribed to treat depression
- You are breast feeding

Do not take this medicine if you are

taking the following medicines:

- pimozone, used for mental problems
- tizanidine, used as a muscle relaxant.
- ramelteon, used to help you sleep

Do not take **FLUVOXIN** if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking **FLUVOXIN**.

- Before you start to use it

Take special care with **FLUVOXIN** and tell your doctor if:

- you are pregnant, or could be pregnant
- you have epilepsy
- you have a history of bleeding problems or if you regularly use medicines which increase the risk of bleeding, such as common pain killers
- you have diabetes
- you are having treatment with electroconvulsive therapy (ECT)
- you ever had mania (a feeling of elation or over-excitement)
- you have liver or kidney problems
- you have high pressure in your eyes (glaucoma)

If you take **FLUVOXIN** near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor should be aware that you are taking **FLUVOXIN** so they can advise you.

If any of the above applies to you, your doctor will tell you whether it is safe for you to start taking **FLUVOXIN**

- Taking other medicines

It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:

- St John's wort
- aspirin (acetylsalicylic acid), used to treat inflammation (arthritis)
- ciclosporin, used to reduce the activity of the immune system
- methadone, used to treat pain and withdrawal symptoms
- mexiletine, used to treat abnormal heart rhythms
- phenytoin or carbamazepine, used to treat epilepsy
- propranolol, used to treat high blood pressure and heart conditions
- ropinirole, for Parkinson's disease.
- a "triptan", used to treat migraines
- terfenadine and astemizole, used to treat allergies. **FLUVOXIN** should not be taken together with terfenadine.
- theophylline, used to treat asthma and breathing problems
- tramadol, a pain-killer
- warfarin or other medicines, used to prevent blood clots
- cisapride, used to treat gastric reflux.

If you are taking or have recently taken any of the medicines in the above list and you have not already discussed these with your doctor, go back to your doctor and ask what you should do. Your dose may need to be changed or you may need to be given a different medicine.

How to use **FLUVOXIN**

- How much to use

Always take **FLUVOXIN** as your doctor has told you to.

You should check with your doctor or pharmacist if you are not sure.

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Usual starting dose for children (8 years and older):

Start with 25mg daily, preferably at bedtime.

The maximum dose in children should not exceed 200mg per day.

Usual starting dose for adults (18 years and older):

Depression:

Start with 50 or 100 mg daily, taken in the evening.

Obsessive compulsive disorder:

Start with 50mg daily, preferably in the evening.

If you don't start to feel better after a couple of weeks, talk to your doctor, who will advise you.

He or she may decide to increase the dose gradually. The highest daily dose that is recommended is 300 mg. If your doctor advises you to take more than 150 mg per day, do not take them all at once; ask your doctor when you should take them.

- When to use it

Swallow the tablets with water. Do not chew them.

You can break the tablets in half if your doctor has advised you to.

- How long to use it

FLUVOXIN may take a little time to start working. Some people do not feel better in the first few weeks of treatment.

Keep taking your tablets until your doctor tells you to stop. Even when you start feeling better, your doctor may want you to carry on taking the tablets for some time, for at least six months to make sure that the medication has worked completely.

Do not stop taking FLUVOXIN too quickly.

You may suffer from withdrawal symptoms such as:

- agitation and anxiety
- confusion
- diarrhoea
- difficulty sleeping
- dizziness
- emotional instability
- headaches
- irritability
- nausea and/or vomiting
- palpitation (faster and stronger heartbeats)
- sensory disturbance (such as electric shock sensations or visual disturbances)
- sweating
- tremors

When stopping FLUVOXIN your doctor will help you to reduce your dose slowly over a number of weeks or months, this should help reduce the chance of withdrawal effects. Most people find that any symptoms on stopping FLUVOXIN are mild and go away on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer.

If you get withdrawal effects when you are coming off your tablets your doctor may decide that you should come off them more slowly. If you get severe withdrawal effects when you stop taking FLUVOXIN, please see your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

If you experience any symptoms on stopping the treatment, contact your doctor.

- If you forget to use it

Do not take a double dose to make up for the forgotten tablet. Take the next tablet at your regular time on the next day. If you are worried

about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you have taken more FLUVOXIN than you should or if someone else has taken your medicine, tell your doctor or pharmacist or contact your nearest hospital.

Symptoms of overdose include, but are not limited to, nausea, vomiting, diarrhoea and feeling drowsy or dizzy. Heart related events (slow or fast heartbeat, low blood pressure), liver problems, convulsions and coma have also been reported.

While you are using it

- Things you must do

Tell all the doctors, dentists, and pharmacists treating you that you are taking FLUVOXIN. Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Pregnancy and breast feeding

- Do not take FLUVOXIN if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take FLUVOXIN if you are breast feeding or plan to breastfeed your baby, because it is known that the medicine passes into breast milk.

Driving and using machines

You can drive and use machines while you are taking this treatment, so long as this medicine does not make you sleepy.

Taking FLUVOXIN with food and drink

You should not consume alcohol during treatment with FLUVOXIN tablets since it may affect the effect of FLUVOXIN tablets.

- Things to be careful of

Occasionally, thoughts of restlessness for example, you cannot sit or stand still (akathisia) may occur or may increase during the first few weeks of treatment

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with **FLUVOXIN**, until the antidepressant effect has worked. Tell your doctor immediately if you experience these symptoms. Then a dosage adjustment may be helpful.

Thoughts of suicide and worsening of your depression or anxiety disorder. If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Tell your doctor immediately if you have any distressing thoughts or experiences.

Use in children and adolescents under 18 years of age

Children and adolescents under 18 years should not take this medicine, unless they are being treated for OCD.

This is because **FLUVOXIN** is not used to treat depression in people aged under 18 years.

Side effects

Like all medicines, **FLUVOXIN** can cause side effects, although not everybody gets them.

Side effects specifically related to **FLUVOXIN**

Common side effects (affects 1 to 10 users in 100):

- agitation
- anxiety
- constipation
- diarrhoea
- difficulty sleeping
- dizziness
- dry mouth
- faster heart beat
- feeling drowsy
- feeling unwell
- headache
- indigestion
- loss of appetite
- nervousness
- stomach pain
- increased sweating
- tremor
- weakness
- vomiting

Uncommon side effects (affects 1 to 10 users in 1,000):

- allergic skin reactions (including swelling of face, lip or tongue, rash or itching)
- confusion
- delayed ejaculation
- dizziness when standing up too quickly
- hallucinations
- lack of co-ordination
- muscle or joint pain

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your

doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of **FLUVOXIN**

- Storage

Keep this medicine out of the sight and reach of children. Store below 30°C and protect from direct sunlight.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

The **FLUVOXIN** 50 mg tablet is yellow coloured, caplet shaped, film-coated tablet with breakline on one side and plain on other side. The tablet can be divided into equal halves.

The **FLUVOXIN** 100 mg tablet is yellow coloured, circular, bioconvex, film-coated tablet having a breakline marking on one side and plain on other side. The tablet can be divided into equal halves.

FLUVOXIN 50mg and 100mg are available in packs of 3 x 10's.

- Ingredients

- Active ingredient(s)

- Fluvoxamine maleate 50mg/100mg

- Inactive ingredients

- Mannitol
- Maize starch
- Pregelatinized starch
- Microcrystalline cellulose (M101)
- Purified water

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- Microcrystalline cellulose (M102)
- Sodium stearyl fumarate
- Colloidal silicone dioxide
- Opadry Yellow YS-1-12526A

- MAL number:

**FLUVOXIN 50mg Film Coated
Tablets (MALXXXXXXXXAZ)**

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Tablets (MALXXXXXXXXAZ)**

Manufacturer / Product

Registration Holder

Ranbaxy (Malaysia) Sdn Bhd
Lot 23, Bakar Arang Industrial
Estate,
08000 Sungai Petani,
Kedah, Malaysia

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