

Package leaflet: Information for the user
Fluvoxamine 50mg Film-Coated Tablets
Fluvoxamine 100mg Film-Coated Tablets
Fluvoxamine maleate
(Refer to as Fluvoxamine Tablets in this leaflet)

Fluvoxamine Tablets treat depression and Obsessive Compulsive Disorder (OCD). Like all medicines it can have unwanted effects. It is therefore important that you and your doctor weigh up the benefits of treatment against the possible unwanted effects, before starting treatment.

Fluvoxamine Tablets should not be used to treat depression in children and adolescents. See section 2, Use in children and adolescents.

Fluvoxamine Tablets won't work straight away. Some people taking antidepressants feel worse before feeling better. Your doctor should see you regularly during your course of treatment. Tell your doctor if you haven't started feeling better.

Some people who are depressed or anxious think of harming or killing themselves. If you start to feel worse, or think of harming or killing yourself, **see your doctor or go to a hospital straight away. See section 2**

Don't stop taking Fluvoxamine Tablets without talking to your doctor. If you stop taking Fluvoxamine Tablets suddenly or miss a dose, you may get withdrawal effects. See section 3 for further information.

If you feel restless and feel like you can't sit or stand still, tell your doctor. Increasing the dose of Fluvoxamine Tablets may make these feelings worse. See section 4, Possible side-effects.

Taking some other medicines with Fluvoxamine Tablets can cause problems. You may need to talk to your doctor. See section 2, Taking other medicines.

If you are pregnant or planning to get pregnant, talk to your doctor. See section 2 Pregnancy and breastfeeding.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fluvoxamine Tablets are and what they are used for
2. What you need to know before you take Fluvoxamine Tablets
3. How to take Fluvoxamine Tablets
4. Possible side effects

5. How to store Fluvoxamine Tablets
6. Contents of the pack and other information

1. What Fluvoxamine Tablets are and what they are used for

Fluvoxamine Tablets belong to a group of medicines called selective serotonin reuptake inhibitors (SSRI).

This medicine contains a substance called fluvoxamine. This is an antidepressant. It is used to treat depression (major depressive episode).

Fluvoxamine Tablets can also treat people who have Obsessive compulsive disorder (OCD).

2. What you need to know before you take Fluvoxamine Tablets

Do not take **Fluvoxamine Tablets** if any of the following applies to you:

- if you are allergic to fluvoxamine or any of the other ingredients of this medicine (listed in section 6)
- if you are taking other medicines called monoamine oxidase inhibitors (MAOI) sometimes prescribed to treat depression or anxiety, including linezolid (an antibiotic which is also an MAOI).

Treatment with fluvoxamine should only be started at least two weeks after discontinuation of an irreversible MAOI. However treatment with fluvoxamine after discontinuation of certain reversible MAOIs can be started the following day. In exceptional cases linezolid (an antibiotic MAOI) may be used with fluvoxamine provided the doctor can monitor you closely. Your doctor will advise you how you should begin taking Fluvoxamine Tablets once you have stopped taking the MAOI.

- if you are taking tizanidine, a medicine often used as muscle relaxant
- if you are taking pimozide, a neuroleptic drug that is used for the treatment of schizophrenia and other psychiatric diseases
- if you are breast-feeding.

If any of the above apply to you, **do not take** Fluvoxamine Tablets and talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluvoxamine Tablets:

- if you recently had a heart attack
- if you are pregnant, or could be pregnant
- if you have epilepsy
- if you have a history of bleeding problems or if you regularly use medicines which increase the risk of bleeding, such as common pain killers, or if you are pregnant (see 'Pregnancy¹')
- if you have diabetes
- if you are having treatment with electroconvulsive therapy (ECT)
- if you have ever had mania (a feeling of elation or over-excitement)
- if you have liver or kidney problems
- if you have high pressure in your eyes (glaucoma)
- if you are less than 18 years old (see also Section 3 How to take Fluvoxamine Tablets).
- If you are taking medicinal products containing buprenorphine or buprenorphine/naloxone, as these products taken in combination with Faverin may lead to serotonin syndrome, a

potentially life-threatening condition (for symptoms, see section 4, “Possible side effects”) see also “Other medicines and Faverin”.

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

Medicines like Fluvoxamine Tablets (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

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 with Fluvoxamine Tablets, until the antidepressant effect has worked.

Tell your doctor immediately if you experience these symptoms. Then a dosage adjustment may be helpful.

Severe skin reactions have been reported when using fluvoxamine. **Stop taking** fluvoxamine and contact a doctor immediately if you develop a rash or mucous membrane lesions. The severe rashes may include rash starting on the extremities, usually on both sides of the body and evolving into centric circles that resemble a target (erythema multiforme), widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis).

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.

Children and adolescents

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

This is because Fluvoxamine Tablets is not used to treat depression in people aged under 18 years.

When taking this type of medicine, people under 18 have an increased risk of side effects such as attempting suicide, thoughts about suicide and hostility, such as aggression, oppositional behaviour and anger.

If your doctor has prescribed Fluvoxamine Tablets for someone under 18 years and you want to discuss this, please go back to your doctor.

You should tell your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Fluvoxamine Tablets.

Also, it is not known whether taking Fluvoxamine Tablets under the age of 18 years can affect growth, maturation or development of intelligence or behaviour in the long term.

Other medicines and Fluvoxamine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without prescription.

- You should not start to take the herbal remedy St John's Wort while you are being treated with Fluvoxamine Tablets since this may result in an increase of undesirable effects. If you are already taking St John's Wort, when you start on Fluvoxamine Tablets, stop taking the St John's Wort and tell your doctor at your next visit
- If you have been taking a medicine to treat depression or anxiety within the last two weeks, or you suffer from schizophrenia, check with your doctor or pharmacist.

Your doctor or pharmacist will check if you are taking other medicines to treat your depression or related conditions, these may include:

- benzodiazepines
- tricyclic antidepressants
- neuroleptic or anti-psychotics
- lithium
- tryptophan
- monamine oxidase inhibitors (MAOIs) such as moclobemide
- pimozide
- selective serotonin reuptake inhibitors (SSRI) such as citalopram.

Your doctor will tell you if it is safe for you to start taking Fluvoxamine Tablets.

You should also tell your doctor or pharmacist if you have been taking **any of the medicines listed** below:

- aspirin (acetylsalicylic acid) or aspirin-like medicines, used to treat pain and 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, such as sumatriptan

- terfenadine, used to treat allergies. Fluvoxamine Tablets should not be taken together with terfenadine
- sildenafil, used to treat erectile dysfunction
- theophylline, used to treat asthma and bronchitis
- tramadol, a pain-killer
- buprenorphine or buprenorphine/naloxone
- clopidogrel, warfarin, nicoumalone or any other drug used to prevent blood clots.

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.

Please tell your doctor or pharmacist if you are taking or have taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Fluvoxamine Tablets with food, drink and alcohol

Do not drink alcohol if you are taking this medicine. This is because alcohol works together with Fluvoxamine Tablets and will make you sleepy and unsteady.

If you normally drink a lot of tea, coffee and soft drinks with caffeine in them, you may have symptoms such as your hands shaking, fast heart rate (palpitations), feeling sick, restlessness and difficulty sleeping (insomnia). If you lower how much caffeine you drink, these symptoms may disappear.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There is only limited experience concerning the use of fluvoxamine during pregnancy.

Do not take fluvoxamine while you are pregnant, unless your doctor considers it absolutely necessary.

If you are currently taking fluvoxamine and are planning to become pregnant or to father a child, please consult with your physician to decide if an alternative medication is necessary or appropriate.

Make sure your midwife and/or doctor know you are on fluvoxamine. 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 new born (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 should not discontinue treatment with fluvoxamine abruptly. If you are taking fluvoxamine in the last 3 months of pregnancy, your baby might have some other symptoms when it is born in addition to having trouble breathing or bluish skin, such as not being able to sleep or feed properly, being too hot or cold, being sick, crying a lot, stiff or floppy muscles, lethargy, drowsiness, tremors, jitters or fits. If your baby has any of these symptoms when it is born contact your doctor immediately.

If you take Fluvoxamine Tablets 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 or mid-wife should be aware that you are taking Fluvoxamine Tablets so they can advise you.

Breast-feeding

Fluvoxamine passes into breast milk. There is a risk of an effect on the baby. Therefore, you should discuss the matter with your doctor, and he/she will decide whether you should stop breast-feeding or stop the therapy with Fluvoxamine Tablets.

Fertility

Fluvoxamine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

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.

Fluvoxamine Tablets contain sodium:

This medicinal product contains less than 1 mmol sodium (23mg) per tablet, i.e. essentially 'sodium free'.

3. How to take Fluvoxamine Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Recommended doses

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

The treatment for depression:

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

The treatment for 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 300mg.

If your doctor advises you to take more than 150mg per day, **do not take** them all at once; ask your doctor when you should take them.

The usual dose for children and adolescents with obsessive compulsive disorder - OCD (8 years and older is):

Start with 25mg (half a tablet) per day, preferably at bedtime. Your doctor may increase the dose every 4 - 7 days in 25mg increments as tolerated until an effective dose is achieved. The highest daily dose is 200mg.

If your doctor advises you to take more than 50mg per day, **do not take** them all at once; ask your doctor when you should take them. If the dose is not divided equally, the larger dose should be taken at night.

Children and adolescents under the age of 18 **should not take** this medicine to treat depression. This medicine should be prescribed for children or adolescents for Obsessive Compulsive Disorder (OCD) **only**.

How to take Fluvoxamine Tablets

- 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 does it take to work?

Fluvoxamine Tablets may take a little time to start working. Some patients do not feel better in the first 2 or 3 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 Fluvoxamine Tablets too quickly.

You may suffer from **withdrawal symptoms** such as:

- agitation and anxiety
- confusion
- diarrhoea
- difficulty sleeping / intense dreams
- dizziness
- emotional instability
- headaches
- irritability
- nausea and/or vomiting
- palpitations (faster heartbeat)
- sensory disturbance (such as electric shock sensations or visual disturbances)
- sweating
- tremors.

When stopping Fluvoxamine Tablets 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 Fluvoxamine Tablets 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 Fluvoxamine Tablets, please see your doctor. He or she may ask you to start taking your tablets again and come off them more slowly (see section 4 'Possible Side Effects').

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

If you take more Fluvoxamine Tablets than you should

If you or someone else takes too much Fluvoxamine Tablets (an overdose), talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

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

If you forget to take Fluvoxamine Tablets

If you miss a tablet, wait until the next dose is due.

Do not try to make up for the dose you have missed.

If you stop taking Fluvoxamine Tablets

When stopping Fluvoxamine Tablets 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 Fluvoxamine Tablets 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 Fluvoxamine Tablets, please see your doctor. He or she may ask you to start taking your tablets again and come off them more slowly (see section 4 'Possible Side Effects').

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects related to this type of medicine

Occasionally, **thoughts of suicide or self harm** may occur or may increase in the first few weeks of treatment with Fluvoxamine Tablets, until the antidepressant effect has worked.

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

If you **have several symptoms at the same time** you might have one of the following rare conditions:

- Serotonin syndrome: if you have sweating, muscle stiffness or spasms, instability, confusion, irritability or extreme agitation
- Neuroleptic malignant syndrome: if you have stiff muscles, high temperature, confusion and other related symptoms
- SIADH: if you feel tired, weak or confused and have achy, stiff or uncontrolled muscles
- Severe skin reactions like severe skin rashes or redness, including rash, starting on the extremities, usually on both sides of the body and evolving into concentric circles that resemble a target (erythema multiforme), widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis). The frequency of these side effects is not known (cannot be estimated from the available data).

Stop taking Fluvoxamine Tablets and **contact your doctor immediately**.

If unusual bruising or purple patches appear on your skin or you vomit blood or pass blood in your stool, contact your doctor for advice.

Stopping of fluvoxamine (particularly when abrupt) commonly leads to withdrawal symptoms (see section 3 withdrawal symptoms).

Sometimes patients **feel slightly sick** as Fluvoxamine Tablets begins to work. Although the feeling of sickness is unpleasant, it should soon pass if you keep taking your tablets as prescribed. This may take a few weeks.

Side effects specifically related to Fluvoxamine Tablets

Common: may affect more than 1 in 10 people:

- agitation
- anxiety
- constipation
- diarrhoea
- difficulty sleeping
- dizziness
- dry mouth
- faster heart beat
- feeling drowsy (lethargy)
- feeling unwell (malaise)
- headache
- indigestion
- loss of appetite
- nervousness
- stomach pain
- sweating
- tremor
- muscle weakness (asthenia)
- vomiting.

Uncommon: may affect up to 1 in 100 people

- aggression
- 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.

Rare: may affect up to 1 in 1,000 people

- convulsions
- liver complaints
- mania (a feeling of elation or over-excitement)
- sensitivity to sunlight

- unexpected milk flow.

Other side effects reported (frequency not known):

- akathisia (restlessness)
- abnormal taste
- anorgasmia (failure to achieve orgasm)
- for female patients: disorders with menstruation (monthly bleeding)
- micturition disorders (such as the need to urinate frequently during the day and/or the night, the sudden lack of control over urination during the day and/or the night, or the lack of ability to urinate)
- paraesthesia (tingling or numbness)
- glaucoma (increased pressure in eye)
- dilated pupils
- increase in the hormone prolactin (a hormone that supports milk production in a nursing mother)
- weight changes
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy¹ in section 2 for more information.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

Side effects related to the treatment for OCD, in children and adolescents, no frequencies are given:

- Hypomania (a feeling of elation and over excitement)
- agitation
- convulsions
- difficulty sleeping (insomnia)
- lack of energy (asthenia)
- hyperactivity (hyperkinesia)
- feeling drowsy (somnia)
- indigestion.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluvoxamine Tablets

- Keep out of the sight and reach of children
- Do not store above 25°C. Store in the original container
- Do not use after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

What Fluvoxamine Tablets contain:

The active substance is fluvoxamine maleate. The tablets come in two strengths, 50mg and 100mg.

The other ingredients are mannitol (E421), pregelatinised maize starch, maize starch, sodium stearyl fumarate and Opadry white Y-1-7000 (containing E464 hydroxypropyl methyl cellulose (HPMC), polyethylene glycol (PEG) and titanium dioxide E171).

What Fluvoxamine Tablets look like and the contents of the pack:

Fluvoxamine 50mg Film-Coated Tablets are round white to off-white tablets marked with FX50 and a breakline on one side and CP on the other.

Fluvoxamine 100mg Film-Coated Tablets are white to off-white capsule shaped tablets marked with FX100 and a breakline on one side and CP on the other.

Fluvoxamine 50mg and 100mg Film-Coated Tablets are available in strip packs of 30, 60 and 90 tablets.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Fluvoxamine 50mg Film-Coated Tablets	29831/0096
Fluvoxamine 100mg Film-Coated Tablets	29831/0095

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in October 2023.