Fluvoxamine 50mg, 100mg Tablets
(Fluvoxamine maleate)

- Fluvoxamine treats 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 treatments against the possible unwanted effects, before starting treatment.
- Fluvoxamine should not be used to treat depression in children and adolescents under 18. See section 2 “Use in children and adolescents under the age of 18 years”.
- Fluvoxamine 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.
- Don’t stop taking Fluvoxamine without talking to your doctor. If you stop taking Fluvoxamine suddenly or miss a dose, you may get withdrawal effects. See section 3 “How to take Fluvoxamine”.
- If you feel restless and feel like you can’t sit or stand still, tell your doctor. Increasing the dose of Fluvoxamine may make these feelings worse.
- Taking some other medicines with Fluvoxamine can cause problems. You may need to talk to your doctor. See section 2 “Other medicines and Fluvoxamine”.
- If you are pregnant or planning to get pregnant, talk to your doctor. See section 2 “Pregnancy, breastfeeding and fertility”.

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 is and what it is used for
2. What you need to know before you take Fluvoxamine
3. How to take Fluvoxamine
4. Possible side effects
5. How to store Fluvoxamine
6. Contents of the pack and other information

1. What Fluvoxamine is and what it is used for
Fluvoxamine belongs to a group of medicines called Selective Serotonin Re-uptake Inhibitor (SSRI) antidepressants. SSRI’s work by increasing the levels of the chemical serotonin in the brain. Serotonin is a neurotransmitter (a messenger that carries signals between nerve cells in the brain). After carrying a message, serotonin is usually reabsorbed by the nerve cells (this is known as “reuptake”). SSRIs work by blocking (“inhibiting”) reuptake, enabling more serotonin to pass further messages between nearby nerve cells.

Fluvoxamine is used to treat the following:
- Depressive illness (major depressive episodes)
- Anxiety disorder (Obsessive-Compulsive Disorder [OCD])

2. What you need to know before you take Fluvoxamine
Do not take Fluvoxamine if:
- You are allergic to Fluvoxamine, other SSRI antidepressants or any of the other ingredients of this medicine (see section 6 “Contents of the pack and other information”).
- You are taking tizanidine, a muscle relaxant (see “Other medicines and Fluvoxamine” section)
You are taking Monoamine Oxidase Inhibitors (MAOIs), medicines used to treat depression. Treatment with Fluvoxamine can be started 2 weeks after discontinuing treatment with an irreversible MAOI, or the following day after discontinuing treatment with a reversible MAOI, or the following day after discontinuing treatment with a reversible MAOI (e.g. moclobemide, linezolid). At least 1 week should elapse between discontinuing treatment with Fluvoxamine and starting treatment with any MAOI.

Warnings and precautions
Talk to your doctor before taking Fluvoxamine:
- If you are diabetic as the dose of your diabetic medicine may need to be adjusted.
- If you suffer from liver or kidney disorders, as you should start on a low dose and be carefully monitored.
- If you start to feel restless and cannot sit or stand still (akathisia). This is most likely to occur within the first few weeks of treatment. If you develop these symptoms, increasing the dose may be detrimental and it may be necessary to review the use of Fluvoxamine.
- If you have recently had a heart attack (myocardial infarction).
- If you have a history of convulsive disorders. Fluvoxamine should be discontinued. Treatment with Fluvoxamine should be avoided if you have unstable epilepsy. If your epilepsy is controlled you should be carefully monitored. Treatment with Fluvoxamine should be discontinued if fits (seizures) occur or if frequency increases.
- If you have a history of mania feeling/being elated or over-excited), which causes unusual behaviour. If you have a manic phase treatment with Fluvoxamine may need to be discontinued.
- If you have a history of bleeding disorders or if you are taking medicines which may increase the risk of bleeding (see “Other medicines and Fluvoxamine”), or if you are pregnant (see “Pregnancy”).
  - Medicines used to treat mental health problems (anti-psychotics)
  - Phenothiazines, medicines used to treat serious mental and emotional disorders and also severe nausea (feeling sick) and vomiting (being sick)
  - Most tricyclic antidepressants, medicines used to treat depression
  - Aspirin, a medicine used to treat mild to moderate pain, to reduce fever or inflammation
  - Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), medicines used to treat certain rheumatic disorders
- If you are receiving ECT (Electro-Convulsive Therapy) treatment.
- If you are taking serotonergic medicines (antidepressants) and/or neuroleptic (anti-psychotic) medicines as on rare occasions, development of serotonin syndrome or neuroleptic malignant syndrome have occurred (see ‘Other medicines and Fluvoxamine” section). As these syndromes may result in potentially life-threatening conditions, treatment with Fluvoxamine should be discontinued if such symptoms (fever (hyperthermia), muscle stiffness, involuntary muscle twitching (myoclonus), confusion, irritability, extreme agitation, delirium and coma) should occur.
- If you are taking linezolid (an antibiotic which is a reversible relatively weak non-selective MAOI – see “Other medicines and Fluvoxamine” section). In exceptional circumstances linezolid can be given in combination with Fluvoxamine but you should be closely monitored.
- If you are at risk of abnormally low levels of salt (sodium) in the blood (hyponatremia), particularly if you are an older person.
- If you have or at risk of increased pressure in the eye (glaucoma) as Fluvoxamine can cause dilation of the pupils (mydriasis).
- If you are an older person, your dose of Fluvoxamine should be increased more slowly and with extra caution.
- Medicines like Fluvoxamine (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Withdrawal symptoms (following discontinuation of treatment with Fluvoxamine)
See section 3 “If you stop taking Fluvoxamine” and section 4 “Possible side effects”. The risk of withdrawal symptoms may be dependent on the duration and dose of treatment and the rate of dose reduction.

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.

Use in children and adolescents under the age of 18 years:
Fluvoxamine should not be used in the treatment of children and adolescents under the age of 18 years, except for patients over 8 years with Obsessive-Compulsive Disorder (OCD). Patients under the age of 18 years are at an increased risk of suicide-related behaviours (suicide attempt and suicidal thoughts) and hostility (predominantly aggression, oppositional behaviour and anger) when treated with antidepressants. If a decision to treat with Fluvoxamine is taken, the patient should be carefully monitored for the appearance of suicidal symptoms. Additionally, limited evidence is available concerning long-term effect on safety in children and adolescents, including effects on growth, puberty and mental, emotional and behavioural developments.

Other medicines and Fluvoxamine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which may interact with or be affected by Fluvoxamine:
- Monoamine Oxidase Inhibitors (MAOIs), including linezolid, medicines used to treat depression (see “Do not take Fluvoxamine” section)
- Selective Serotonin Reuptake Inhibitors, medicines used to treat depression
- Lithium, a medicine used to treat mood disorders (antipsychotic)
- Tryptophan, a dietary supplement
- Medicines used to treat migraines and cluster headaches (triptans)
- Tramadol, a pain-relieving medicine
- St. John’s Wort, a herbal remedy used to treat depression
- Medicines used to treat depression e.g. clomipramine, imipramine, amitriptyline (tricyclic antidepressants). A decrease in the dose of these medicines should be considered if treatment with Fluvoxamine is started
- Medicines used to treat mental health disorders e.g. clozapine, olanzapine, quetiapine, thioridazine (neuroleptics). A decrease in the dose of these medicines should be considered if treatment with Fluvoxamine is started
- Tizanidine, a muscle relaxant (see “Do not take Fluvoxamine” section)
- Tacrine, a medicine used to treat mild to moderate dementia
- Theophylline, a medicine used to treat breathing disorders
- Methadone, a synthetic opiate used as a treatment for opioid dependency
- Mexiletine and propranolol, medicines used to treat heart disorders
- Ropinirole, a medicine used to treat Parkinson’s Disease
- Caffeine (see “Taking Fluvoxamine with food and drink and alcohol” section)
- Phenytoin, carbamazepine, medicines used to treat and prevent fits (seizures)
- Terfenadine, astemizole, medicines used to treat allergic conditions
- Cisapride, a medicine used to treat gastrointestinal disorders
- Sildenafil, a medicine used to treat erectile dysfunction
- Ciclosporin, a medicine used to reduce the body’s immunity when receiving organ transplant
- Medicines used to calm and relieve anxiety disorders e.g. triazolam, midazolam, alprazolam and diazepam (benzodiazepines). The dose of these benzodiazepines should be reduced during co-administration with Fluvoxamine
- Warfarin, a medicine used to thin the blood (anticoagulant) as the risk of haemorrhage may increase
- Clopidogrel, used to prevent blood clots

**Taking Fluvoxamine with food and drink and alcohol**
- It is not recommended to drink alcohol whilst taking Fluvoxamine.
- You should lower your intake of caffeine-containing beverages (tea, coffee, cola etc) when taking Fluvoxamine as adverse effects like shakiness (tremor), feeling your heartbeat (palpitations), feeling sick (nausea), restlessness and difficulty in sleeping (insomnia) may occur.

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

**Pregnancy**
Fluvoxamine should not be used if you are attempting to conceive a baby or if you are pregnant unless your clinical condition requires treatment with Fluvoxamine.

When taking Fluvoxamine during pregnancy, particularly in the last months of pregnancy, there is an increased risk of the development of a very serious condition in babies, called Persistent Pulmonary Hypertension in the Newborn (PPHN). This occurs when the baby does not change over from foetal to normal newborn circulation which decreases the baby’s supply of oxygen.

Isolated cases of withdrawal symptoms in newborn children have been reported following the use of Fluvoxamine at the end of pregnancy.

Following treatment with Fluvoxamine during the last 3 months of pregnancy, some newborns have experienced feeding and/or breathing difficulties, fits (seizures), temperature instability, low blood sugar levels (hypoglycaemia), shakiness (tremor), abnormal muscle tone, jitteriness, abnormal blue discoloration of the skin (cyanosis), irritability, a lack of energy (lethargy), sleepiness or drowsiness (somnolence), being sick (vomiting), difficulty in sleeping and constant crying and may require prolonged hospitalisation.

If you take Fluvoxamine 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 midwife should be aware that you are taking Fluvoxamine so they can advise you.

**Breast-feeding**
If you are breast-feeding, Fluvoxamine should not be taken as Fluvoxamine is passed into breast milk.

**Fertility**
Fluvoxamine should not be used if you are attempting to conceive a baby unless your clinical condition requires treatment with Fluvoxamine.

**Driving and using machines**
Fluvoxamine may cause sleepiness or drowsiness (somnolence). If symptoms are experienced, it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required.

**Fluvoxamine contains lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. **How to take Fluvoxamine**
Always take Fluvoxamine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The tablets should be swallowed without chewing and with water.
• The score line on the tablet is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

**Depression**

**Adults:**
- The recommended dose is 100mg daily.
- The starting dose is 50mg or 100mg, given as a single dose in the evening.
- Your dose should be reviewed and adjusted if necessary within 3 to 4 weeks of starting treatment with Fluvoxamine.
- It is recommended to increase the dose gradually until an effective dose is reached.
- If after some weeks on the recommended dose, insufficient response has been achieved, the dose may be increased gradually up to a maximum of 300mg daily.
- Doses up to 150mg can be given as a single dose, preferably in the evening. Doses above 150mg should be given in 2 or 3 divided doses.
- Treatment should be continued for at least 6 months after recovery from a depressive episode.

**Children and adolescents under the age of 18 years:**
Fluvoxamine should **not be used** for the treatment of major depressive episodes in children and adolescents under the age of 18 years of age (see "Warnings and precautions" section).

**Obsessive-Compulsive Disorders (OCD)**

**Adults:**
- The recommended dose is between 100mg and 300mg daily.
- The starting dose is 50mg per day.
- If after some weeks on the recommended dose, insufficient response has been achieved, the dose may be increased gradually up to a maximum of 300mg daily.
- Doses up to 150mg can be given as a single dose, preferably in the evening. Doses above 150mg should be given in 2 or 3 divided doses.
- If no improvement is observed within 10 weeks, treatment with Fluvoxamine should be reconsidered.

**Children and adolescents under the age of 18 years:**
- The starting dose is 25mg per day.
- Increase every 4-7 days in 25mg increments until an effective dose is achieved.
- The maximum dose in children should not exceed 200mg per day.
- It is advisable that a total daily dose of more than 50mg should be given in two divided doses. If the two divided doses are not equal, the larger dose should be given at bedtime.

**Patients with liver and/or kidney disorders**
You should start on a low dose and be carefully monitored.

**Withdrawal symptoms (following discontinuation of treatment with Fluvoxamine)**
See "If you stop taking Fluvoxamine" section and section 4 “Possible side effects”.

**If you take more Fluvoxamine than you should**
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you. **Symptoms of overdose include:** feeling sick (nausea), being sick (vomiting), diarrhoea, sleepiness or drowsiness (somnolence), dizziness, faster heartbeat (tachycardia), slower heartbeat (bradycardia), low blood pressure (hypotension), liver function disturbances, fits (convulsions) and coma.

**If you forget to take Fluvoxamine**
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

**If you stop taking Fluvoxamine**
- It is important to keep taking Fluvoxamine for as long as your doctor has told you to.
- Abrupt discontinuation should be avoided.
When stopping treatment with Fluvoxamine the dose should be gradually reduced over a period of at least 1 or 2 weeks in order to reduce the risk of withdrawal reactions (see section 4 “Possible side effects”).

If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment of Fluvoxamine, then resuming the previously prescribed dose may be considered or continuing to decrease the dose, but at a more gradual rate.

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

4. Possible side effects
Like all medicines, Fluvoxamine can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:
- Distressing thoughts of harming yourself or committing suicide
- Allergic reactions; swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Syndrome of Inappropriate Anti-Diuretic Hormone secretion (SIADH). Anti-Diuretic Hormone (ADH) is produced by the brain and is stored in & released by the pituitary gland. ADH controls how your body releases and conserves water. SIADH occurs when ADH is produced somewhere other than the brain, which makes it difficult for your body to get rid of excess water. This causes a build-up of fluids as well as abnormally low sodium levels
- Neuroleptic malignant syndrome-like effects (a group of symptoms together e.g. rigidity, fever, sweating, high blood pressure, agitation, delirium, coma)

Common side effects (may affect up to 1 in 10 people)
- General weakness (asthenia)
- Generally feeling unwell (malaise)
- Feeling your heartbeat (palpitations)
- Faster heartbeat (tachycardia)
- Abdominal pain
- Constipation
- Diarrhoea
- Dry mouth
- Indigestion (dyspepsia)
- Feeling sick (nausea). This usually diminishes within the first 2 weeks of treatment
- Being sick (vomiting)
- Restlessness (agitation)
- Dizziness
- Headache
- Difficulty in sleeping (insomnia)
- Nervousness
- Sleepiness or drowsiness (somnolence)
- Shakiness (tremor)
- Anxiety
- Sweating, excessive sweating (hyperhidrosis)
- Loss of appetite (anorexia)

Uncommon side effects (may affect up to 1 in 100 people)
- Low blood pressure when changing position (orthostatic hypotension)
- Pain or swelling in the joints (arthritis)
- Muscle pain (myalgia)
- Lack of voluntary co-ordination of muscle movements [unsteadiness or clumsiness] (ataxia)
- Medicine-induced movement disorders (Extrapyramidal Symptoms [EPS])
- Confusional stage
- Seeing or hearing things that are not real (hallucinations)
- Aggression
- Delayed ejaculation
- Skin disorders (rash, severe itching [pruritis])
Rare side effects (may affect up to 1 in 1000 people)
- Liver function disorders
- Fits (convulsions)
- Feeling/being elated or over-excited, which causes unusual behaviour (mania)
- Milky secretion from the breasts not due to breast-feeding (galactorrhoea)
- Abnormal sensitivity of the skin to sunlight (photosensitivity)

Other side effects (frequency not known)
- Bleeding from the stomach, gums or bottom (gastrointestinal haemorrhage)
- Excessive bleeding from the vagina (gynaecological haemorrhage)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “Pregnancy” in section 2 for more information
- Bruising (ecchymosis)
- Skin rash caused by small blood vessels bleeding into the skin (purpura)
- Abnormally high levels of prolactin in the blood (hyperprolactinaemia)
- Abnormally low levels of salt (sodium) in blood (hyponatremia)
- Weight gain or loss
- Serotonin syndrome (a group of symptoms together e.g. abnormally high body temperature, rigidity, muscle spasms, confusion, irritability, agitation)
- Tingling or numbness in the hands or feet (paraesthesia)
- Taste disturbances
- Extreme restlessness accompanied by an increase in muscle spasms, tremors and twitching (psychomotor restlessness) or restlessness (akathisia)
- Increased pressure in the eye (glaucoma)
- Dilation of the pupil of the eye (mydriasis)
- Bruising (ecchymosis)
- Skin rash caused by small blood vessels bleeding into the skin (purpura)
- Abnormally high levels of prolactin in the blood (hyperprolactinaemia)
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- Taste disturbances
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- Increased pressure in the eye (glaucoma)
- Dilation of the pupil of the eye (mydriasis)
- Bone fractures
- Difficulty reaching orgasm even after sexual stimulation (anorgasmia)
- Menstrual disorders including lack of menstrual periods (amenorrhrea), extremely light menstrual blood flow (hypomenorrhoea), bleeding from the uterus between menstrual periods (metrorrhagia), abnormally heavy and prolonged menstrual period at regular intervals (menorrhagia)
- Urinary (micturition) disorders including urinary retention, incontinence, frequent need to urinate (pollakiuria), a need to wake and pass urine at night (nocturia) and repeated inability to control urination (enuresis)
- In children and adolescents with Obsessive Compulsive Disorder (OCD), reported adverse effects included difficulty in sleeping (insomnia), general weakness (asthenia), restlessness (agitation), abnormal amount of uncontrolled muscular action (hyperkinesia), sleepiness or drowsiness (somnolence), indigestion (dyspepsia) and feeling over-excited (hypomania). Convulsions have also been reported
- Withdrawal symptoms in newborn children (see “Pregnancy” section)

Withdrawal symptoms
Discontinuation of Fluvoxamine (particularly when abrupt) commonly leads to withdrawal symptoms. Dizziness, sensory disturbances (including tingling or numbness in the hands or feet [paraesthesia], visual disturbances and electric shock sensations), sleep disturbances (including difficulty in sleeping [insomnia] and intense dreams), restlessness (agitation) and anxiety, irritability, confusion, emotional instability, feeling sick (nausea) and/or being sick (vomiting) and diarrhoea, sweating and palpitations, headache and tremor are the most commonly reported. Generally these symptoms are mild to moderate, however, in some patients they may be severe and/or prolonged. They usually occur within the first few days of discontinuing treatment. Generally, these symptoms usually resolve within 2 weeks, though in some patients they may be prolonged (2-3 months or more). It is therefore advised to discontinue treatment gradually over a period of several weeks or months.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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**
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package in order to protect from light and moisture.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. **Contents of the pack and other information**

**What Fluvoxamine contains:**
- Each 50mg tablet contains 50mg of fluvoxamine maleate
- Each 100mg tablet contains 100mg of fluvoxamine maleate

**The other ingredients are:** lactose monohydrate, mannitol, maize starch, hypromellose, polyethylene glycol 4000, pregelatinized starch, sodium stearyl fumarate, colloidal anhydrous silica, titanium dioxide (colouring agent E 171)

**What Fluvoxamine look like and contents of the pack:**
- Fluvoxamine 50mg are white, biconvex, round, scored, film-coated tablets with a diameter 8.8 - 9.2mm and height of 3.6 - 4.1mm
- Fluvoxamine 100mg are white, biconvex, round, scored, film-coated tablets with a diameter 11.8 - 12.2mm and height of 4.8 – 5.2mm

**Fluvoxamine is available in:**
Fluvoxamine tablets are available in packs of 15, 20, 30, 40, 50, 60, 90, or 100 tablets.

Not all pack sizes may be marketed.

**Product Licence Numbers:**
- Fluvoxamine 50mg Tablets: PL 11311/0488
- Fluvoxamine 100mg Tablets: PL 11311/0489

**Marketing Authorisation Holder:**
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**Manufacturer:**
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