

**Package leaflet: Information for the user**  
**FLUOXETINE 60MG CAPSULES**  
fluoxetine

**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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Fluoxetine Capsules are and what they are used for
2. What you need to know before you take Fluoxetine Capsules
3. How to take Fluoxetine Capsules
4. Possible side effects
5. How to store Fluoxetine Capsules
6. Contents of the pack and other information

**1. What Fluoxetine Capsules are and what they are used for**

The name of your medicine is Fluoxetine 60mg Capsules (called fluoxetine throughout this leaflet). Fluoxetine belongs to a group of medicines called ‘selective serotonin reuptake inhibitor (SSRI) antidepressants’. They are used to treat the following conditions **in adults**: -

- the symptoms of depression and any feelings of anxiety
- the symptoms of obsessive-compulsive disorder (OCD)
- the eating disorder Bulimia nervosa: for the reduction of binge-eating and purging activity.

How Fluoxetine Capsule works

Everyone has a substance called serotonin in their brain. People who are depressed or have obsessive compulsive disorder or bulimia nervosa have lower levels of serotonin than others. It is not fully understood how Fluoxetine and other SSRIs work but they may help by increasing the level of serotonin in the brain. Treating these conditions is important to help you get better. If it's not treated, your condition may not go away and may become more serious and more difficult to treat. You may need to be treated for a few weeks or months to ensure that you are free from symptoms.

**2. What you need to know before you take Fluoxetine Capsules**

You should not take fluoxetine until you are sure it is safe for you to do so.

**Do not take fluoxetine capsules :**

- if you are allergic to fluoxetine hydrochloride or any of the other ingredients of fluoxetine capsules (listed in Section 6 below). **If you develop a rash or other allergic**

**reactions (like itching, swollen lips or face or shortness of breath), stop taking the capsules straight away and contact your doctor immediately**

- if you are taking other medicines used to treat depression, known as irreversible, non-selective monoamine oxidase inhibitors (MAOIs) since serious or even fatal reactions can occur. Examples of MAOIs include nialamide, iproniazide, phenelzine, tranylcypromine and isocarboxazid .

Treatment with fluoxetine should only be started 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine).

Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking fluoxetine. If fluoxetine has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.

- if you are taking metoprolol (to treat heart failure) since there is an increased risk of your heart beat becoming too slow.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Fluoxetine if you:

- have epilepsy or fits (seizures) or experience an increase in seizure frequency, contact your doctor immediately; fluoxetine might need to be discontinued
- have mania now or in the past; if you have a manic episode, contact your doctor immediately because fluoxetine might need to be discontinued
- have diabetes (your doctor may need to adjust your dose of insulin or other antidiabetic treatment);
- have liver problems (your doctor may need to adjust your dosage)
- have heart problems such as if you or your family have now, or in the past, an irregular heart rate (congenital long QT syndrome)
- are taking diuretics (water tablets), especially if you are elderly
- are having ECT (electro-convulsive therapy) treatment
- have a history of bleeding disorders or you develop bruises or unusual bleeding or if you are pregnant (see 'Pregnancy')
- are taking medicines that thin the blood (see 'Other medicines and Fluoxetine')
- have ongoing treatment with tamoxifen (used to treat breast cancer) (see 'Other medicines and Fluoxetine')
- starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of fluoxetine may make this worse
- start to experience fever, muscle stiffness or tremor, changes in your mental state like confusion, irritability and extreme agitation; you may suffer from the so-called "serotonin syndrome" or "neuroleptic malignant syndrome". Although this syndrome occurs rarely it may result in potentially life threatening conditions; **contact your doctor immediately**, fluoxetine might need to be discontinued
- have glaucoma (increased pressure in the eye)
- have weight loss
- have low resting heart-rate and/or if you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- have rash, fever, redness, breathing difficulty, swelling of limbs. These could be signs of an allergic reaction. Stop taking fluoxetine and tell your doctor if you experience any of these symptoms.
- The use of buprenorphine/opioids together with Fluoxetine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Fluoxetine").

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

### **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.

### **Other medicines and Fluoxetine**

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines (up to 5 weeks ago) including medicines obtained without prescription. Fluoxetine may affect the way some other medicines work (interaction), especially the following:

- metoprolol when used for heart failure; there is an increased risk of your heart beat becoming too slow.
- **mequitazine** (for allergies); because taking this drug with Fluoxetine may increase the risk of changes in the electrical activity of the heart.
- **lithium, selegiline, St. John's wort, tramadol** ( a painkiller ) , **triptans** ( for migraine ) and **tryptophan**; there is an increased risk of serotonin syndrome when these drugs are taken with fluoxetine. Your doctor will carry out more frequent check-ups.
- medicines that may affect the heart's rhythm, e.g. **Class IA and III antiarrhythmics, antipsychotics** (e.g. phenothiazine derivatives, pimozide, haloperidol), **tricyclic antidepressants**, certain **antimicrobial agents** (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), **anti-malaria treatment** particularly halofantrine or certain **antihistamines** (astemizole, mizolastine), because taking one or more of these drugs with Fluoxetine may increase the risk of changes in the electrical activity of the heart.
- **phenytoin** (for epilepsy); because fluoxetine may influence the blood levels of this drug, your doctor may need to introduce phenytoin more carefully and carry out check-ups when given with fluoxetine.
- **flecainide, propafenone, nebivolol** or **encainide** (for heart problems), **carbamazepine** (for epilepsy), **atomoxetine** or **tricyclic antidepressants** (for example **imipramine, desipramine** and **amitriptyline**) or **risperidone** (for schizophrenia); because Fluoxetine may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with fluoxetine.

- **tamoxifen** (used to treat breast cancer), because fluoxetine may change the blood levels of this drug and a reduction of the effect of tamoxifen cannot be excluded, your doctor may need to consider different antidepressant treatments.
- **monoamine oxidase inhibitors A (MAOI-A)** including moclobemide, linezolid (an antibiotic) and methylthionium chloride (also called methylene blue, used for the treatment of medicinal or chemical product induced methemoglobinemia): due to the risk of serious or even fatal reactions (called serotonin syndrome). Treatment with fluoxetine can be started the day after stopping treatment with reversible MAOIs but the doctor may wish to monitor you carefully and use a lower dose of the MAOI-A drug.
- **anti-coagulants** (such as warfarin), **NSAID** ( such as ibuprofen, diclofenac ), **aspirin** and **other medicines used to thin the blood** (including clozapine, used to treat certain mental disorders); fluoxetine may alter the effect of these medicines on the blood. If fluoxetine treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests, adjust your dose and check on you more frequently.
- **cyproheptadine** (for allergies); because it may reduce the effect of Fluoxetine.
- **drugs that lower sodium levels in the blood** (including, drug that causes increase in urination, desmopressin, carbamazepine and oxcarbazepine); because these drugs may increase the risk of sodium levels in the blood becoming too low when taken with Fluoxetine.
- **anti-depressants** such as tricyclic anti-depressants, other selective serotonin reuptake inhibitors (SSRIs) or bupropion, **mefloquine** or **chloroquine** (used to treat malaria),
- **buprenorphine/opioids**: These medicines may interact with Fluoxetine and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- **tramadol** (used to treat severe pain) or **anti-psychotics** such as phenothiazines or butyrophenones; because Fluoxetine may increase the risk of seizures when taken with these medicines.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking fluoxetine.

### **Taking fluoxetine with food , drink and alcohol**

- you can be take Fluoxetine with or without food.
- you should avoid alcohol while you are taking fluoxetine.

### **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*

It is preferable not to use this treatment during pregnancy unless the potential benefit outweighs the potential risk. Thus, you and your doctor may decide to gradually stop taking fluoxetine while you are pregnant or before being pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking fluoxetine.

In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the

heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took fluoxetine.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like fluoxetine 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.

If you take Fluoxetine 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 Fluoxetine so they can advise you.

Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in new born children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping.

#### *Breast-feeding*

Fluoxetine is excreted in breast milk and can cause side effects in babies. You should only breast-feed if it is clearly necessary. If breast-feeding is continued, your doctor may prescribe a lower dose of fluoxetine.

#### *Fertility*

Fluoxetine 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:**

Antidepressants such as fluoxetine can affect your judgement or co-ordination. Fluoxetine may affect your ability to drive, operate machinery and carry out other hazardous activities and should therefore be avoided until you know how fluoxetine affects you.

### **3. How to take Fluoxetine Capsules**

Always take fluoxetine exactly as your doctor has told you. You should check with your doctor if you are not sure.

#### *Adults:*

The recommended dose is:

*Depression:* The recommended dose is 20 mg daily. Your doctor will review and adjust your dosage if necessary within 3 to 4 weeks of the start of treatment. If required, the dosage can be gradually increased up to a maximum of 60 mg daily. The dose should be increased carefully to ensure that you receive the lowest effective dose. You may not feel better immediately when you first start taking your medicine for depression. This is usual because an improvement in depressive symptoms may not occur until after the first few weeks. Patients with depression should be treated for at least 6 months.

*Bulimia nervosa:* The recommended dose is 60 mg daily.

*OCD:* The recommended dose is 20 mg daily. Your doctor will review and adjust your dosage if necessary after 2 weeks of treatment. If required, the dosage can be gradually increased up to a maximum of 60 mg daily. If no improvement is noted within 10 weeks, your doctor will reconsider your treatment.

**Use in children and adolescents aged 8 to 18 years with depression:**

The use of fluoxetine 60mg capsules in children and adolescents (under the age of 18) is not recommended, as this strength of the formulation is inappropriate.

*Elderly:*

Your doctor will increase the dose with more caution and the daily dose should generally not exceed 40 mg. The maximum dose is 60 mg daily.

*Liver impairment:*

If you have a liver problem or are using other medication that might affect fluoxetine, your doctor may decide to prescribe a lower dose or tell you to use fluoxetine every other day.

**If you take more fluoxetine than you should**

It is important to stick to the dose on the label of the medicine. If you or someone else takes too much medicine, contact your doctor or nearest hospital emergency department immediately. Always take any medicine left over with you and also the box, as this will allow easier identification of the medicine.

Symptoms of an overdose include feeling sick, being sick, seizures, heart problems (like irregular heart beat and cardiac arrest), lung problems and change in mental condition ranging from excitation to coma

**If you forget to take fluoxetine**

If you forget to take a dose, simply take the next dose when it is due. Do not take a double dose to make up for a forgotten dose.

**If you stop taking fluoxetine**

- **do not** stop taking fluoxetine without asking your doctor first, even when you start to feel better. It is important that you keep taking your medicine
- make sure you do not run out of capsules.

You may notice the following effects (withdrawal effects) when you stop taking fluoxetine: dizziness; tingling feelings like pins and needles; sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless or agitated; unusual tiredness or weakness; feeling anxious; nausea/vomiting (feeling sick or being sick); tremor (shakiness); headaches.

Most people find that any symptoms on stopping fluoxetine are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

When stopping fluoxetine, your doctor will help you to reduce your dose slowly over one or two weeks - this should help reduce the chance of withdrawal effects.

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

**4. Possible side effects**

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

**Stop taking fluoxetine and tell your doctor immediately:**

- if you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away (see Section 2)
- if you get a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath, stop taking the capsules straight away and tell your doctor immediately
- if you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose may make you feel worse. **If you feel like this, contact your doctor**
- **tell your doctor immediately** if your skin starts to turn red or you develop a varied skin reaction or your skin starts to blister or peel. This is very rare
- if you experience abnormally high mood
- if you feel excessively happy but may become angry or irritable
- if you have fits
- if you have unexplained vaginal bleeding
- if you have gastrointestinal bleeding.

Some patients have had:

- a combination of symptoms (known as “serotonin syndrome”) including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (only rarely)
- feelings of weakness, drowsiness or confusion mostly in elderly people and in (elderly) people taking diuretics (water tablets)
- prolonged and painful erection
- irritability and extreme agitation
- heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate
- unusual bleeding or bruising - due reduction in blood platelets.

If you have any of the above side effects, you should tell your doctor immediately.

**If you have any of the following symptoms and they bother you, or last for some time, tell your doctor or a pharmacist.**

**Very common** (may affect more than 1 in 10 people)

- insomnia
- headache
- diarrhoea, feeling sick (nausea)
- fatigue.

**Common** (may affect up to 1 in 10 people)

- not feeling hungry, weight loss
- nervousness, anxiety
- restlessness, poor concentration
- feeling tense
- decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity)
- sleep problems, unusual dreams, tiredness or sleepiness
- disturbance in attention

- dizziness
- change in taste
- uncontrollable shaking movements
- blurred vision
- rapid and irregular heartbeat sensations
- flushing
- yawning
- indigestion, vomiting
- dry mouth
- rash, urticaria, itching
- excessive sweating
- joint pain
- passing urine more frequently
- 
- feeling shaky or chills.

**Uncommon** (may affect up to 1 in 100 people)

- feeling detached from yourself
- strange thinking
- orgasm problems
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or co-ordination
- memory loss, difficulty in remembering
- ringing in the ears
- enlarged (dilated) pupils
- low blood pressure
- shortness of breath
- hair loss
- ringing in the ears
- increased tendency to bruising
- difficulty swallowing
- cold sweat
- difficulty passing urine
- malaise
- feeling abnormal
- nose bleeds
- feeling hot or cold.

**Rare** (may affect up to 1 in 1,000 people)

- low levels of salt in the blood
- reduction in the number of white blood cells like neutrophils and leukocytes – report any signs of fever, tiredness as you may have an infection
- reduction in blood platelets, which increases risk of bleeding or bruising
- pain in abdomen indicating inflammation of liver (hepatitis)
- untypical wild behaviour
- hallucinations
- agitation
- panic attacks
- stuttering
- aggression



- problems urinating
- vasculitis (inflammation of a blood vessel)
- rapid swelling of the tissues around the neck, face, mouth and/or throat
- pain in the tube that takes food or water to your stomach
- sensitivity to sunlight
- producing breast milk
- raised prolactin levels in the blood
- muscle pain
- confusion
- lung problems
- abnormal liver function test results
- sore throat.

**Not known:** (frequency cannot be estimated from the available data)

- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information

**Bone fractures** - an increased risk of bone fractures has been observed in patients taking this type of medicines.

If you have any of the symptoms listed and they bother you, or last for some time, tell your doctor or a pharmacist.

Most of these side effects are likely to disappear with continued treatment.

### **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](http://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 Fluoxetine Capsules**

- keep this medicine out of the sight and reach of children
- do not use fluoxetine capsules after the expiry date, which is stated on the end of the carton and on the blisters, after 'Exp'. The expiry date refers to the last day of the month
- store in the original blister in order to protect from moisture
- 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 to protect the environment.

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

### **What fluoxetine capsules contains**

The name of this medicine is Fluoxetine 60mg Capsules. The active substance in your capsules is fluoxetine hydrochloride. Each capsule contains fluoxetine hydrochloride equivalent to 60mg of fluoxetine. Other ingredients include pregelatinised maize starch. The capsule shell is made of

gelatin, sodium lauril sulfate, yellow iron oxide (E172), titanium dioxide (E172) and black edible printing ink, which contains dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide (E172), potassium hydroxide and purified water.

**What fluoxetine capsules looks like and contents of the pack**

Fluoxetine 60mg Capsules are opaque, yellow hard gelatine capsules imprinted with NM. They are filled with a white to off white powder. Fluoxetine 60mg Capsules are supplied in blister packs of 30 capsules.

**Marketing Authorisation Holder**

The Marketing Authorisation holder of these capsules is Focus Pharmaceuticals Limited, Capital House ,85 King William Street, London EC4N 7BL UK.

**Manufacturer**

Mercury Pharmaceuticals Ltd.  
Capital House, 85 King William Street,  
London EC4N 7BL, UK

This leaflet was prepared in December 2020