Package leaflet: Information for the patient

Fluoxetine 60 mg Capsules, Hard

Warning – Thoughts of self- harm and suicidal behaviour – see section 2

Fluoxetine

Eight important things you need to know about Fluoxetine.
Please read all of this leaflet. It includes a lot of additional important information about this medicine.

- **Fluoxetine treats depression and anxiety disorders**. 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. See section 4 'Possible side effects', inside this leaflet.
- **Fluoxetine is not for use in children under 8 years**.
- **Fluoxetine won't work straight away.** Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you have started feeling better. See section 3, 'How to take Fluoxetine'.
- **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 'What you need to know before you take Fluoxetine'.
- **Don't stop taking Fluoxetine without talking to your doctor**. If you stop taking Fluoxetine suddenly or miss a dose, you may get withdrawal effects. See section 3, 'If you stop taking Fluoxetine'.
- **If you feel restless and feel like you can't sit or stand still, tell your doctor**. Increasing the dose of Fluoxetine may make these feelings worse. See section 4, 'Possible side effects'.
- **Taking some other medicines with Fluoxetine can cause problems:** You may need to talk to your doctor. See section 2, 'Other medicines and Fluoxetine'.
- **If you are pregnant or planning to become pregnant**, talk to your doctor. See section 2, 'Pregnancy, breast-feeding 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 Fluoxetine is and what it is used for
2. What you need to know before you take Fluoxetine
3. How to take Fluoxetine
4. Possible side effects
5. How to store Fluoxetine
6. Contents of the pack and other information

1. What Fluoxetine is and what it is used for

Fluoxetine is one of a type of antidepressants known as Selective Serotonin Reuptake Inhibitors (SSRIs). Fluoxetine is used to treat:

Adults:
- The symptoms of depression and feelings of anxiety
- The symptoms of a condition called obsessive-compulsive disorder (OCD)
- The eating disorder bulimia nervosa

Children and adolescents aged 8 years and above (Under specialist supervision only):
- Moderate to severe major depressive disorder, if the depression does not respond to psychological therapy after 4-6 sessions. Fluoxetine should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy.

2. What you need to know before you take Fluoxetine

Do not take Fluoxetine:
- if you are allergic to fluoxetine or any of the other ingredients of this medicine (listed in section 6)**. 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 any medicines known specifically as irreversible, non-selective monoamine oxidase inhibitors (MAO inhibitors). An example of such a medicine is iproniazid, which is used to treat depression.
- if you are taking the medicine metoprolol, used to treat heart failure.

Warnings and precautions
Talk to your doctor or pharmacist before taking Fluoxetine if any of the following applies to you:
- if you are diabetic
- if you suffer from epilepsy or have ever had a fit. Treatment should be discontinued in any patient who develops a fit or who has more fits
- if you have a history of bleeding disorders, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility')
- if you suffer from kidney, liver or heart problems
- if you have disturbances in heart rhythm called QT prolongation (delayed conduction of electrical signals which can be seen on an ECG, an electrical recording of the heart), or a family history of such conditions.
- if you suffer from any conditions that may make you more prone to experiencing changes in your heart beat (e.g. low blood potassium or magnesium levels, a slow heart beat)
- if you suffer from manic phases (overactive behaviour or thoughts). Fluoxetine should be discontinued if you enter a manic phase
- if you are having electro-convulsive treatment (ECT)
- if you have increased pressure in the eye (glaucoma)
- if you start to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Fluoxetine may make this worse
- if you get unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (these are symptoms of 'serotonin syndrome') – see section 4.

Medicines like Fluoxetine may cause symptoms of sexual dysfunction (see section 4). Rarely people can experience more persistent sexual side-effects after they have stopped taking SSRIs. The term 'post SSRI sexual dysfunction' (PSSD) has been used by some people to describe these symptoms. For these people, PSSD can have a significant and distressing impact on their lives. Research is needed to understand why this happens and how common it is. It is important that people experiencing ongoing sexual side-effects receive appropriate and timely support.

Thoughts of suicide and worsening of your depression or anxiety disorder:
This medicine may be associated with thoughts of self-harm and suicidal behaviour in some people. Tell someone you trust, who can help you in an emergency, that you are taking this medicine and ask that they read this leaflet.
Talk to your trusted person, prescriber or go to a hospital straight away, if after starting this medicine, you have new or worse:

- Feelings of anxiety or irritability
- Feelings of restlessness and agitation
- Extreme increases in activity and difficulty sleeping
- Thoughts of acting on dangerous impulses to harm yourself
- Thoughts about suicide or dying
- Changes in behaviour or mood you, or someone you trust, notices and is worried about

In some people, thoughts of self-harm and suicidal behaviour may be increased when first starting antidepressants. Antidepressants take time to work; and sometimes side effects occur before you or others notice improvements in your mood.

Never stop taking an antidepressant suddenly without first talking to a healthcare professional. Stopping an antidepressant medicine suddenly can cause other symptoms related to withdrawal to occur.

Information from clinical trials has shown the highest risk of thoughts of self harm and suicidal behaviour, is in adults aged less than 25 years who were treated with an antidepressant but the risk applies to people of all ages treated with these medicines.

Call NHS 111 who can offer you support, until you can be with someone who can help you in person.

Children and adolescents aged 8 to 18 years
Patients under 18 years of age have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when taking this class of medicines. Fluoxetine should only be used in children and adolescents aged 8 to 18 years for the treatment of moderate to severe major depressive episodes (in combination with psychological therapy); it should not be used to treat other conditions.

Only limited information concerning the long-term safety of fluoxetine on growth, puberty, mental, emotional and behavioural development in this age group is available. Despite this, your doctor may prescribe fluoxetine for patients under 18 for moderate to severe major depressive episode in combination with psychological therapy because he/she decides that this is in their best interests. If your doctor has prescribed fluoxetine for a patient under 18 years of age and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 years of age are taking fluoxetine.

Fluoxetine should not be used in the treatment of children under the age of 8 years.

Other medicines and Fluoxetine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially the following:
Do not take fluoxetine with:

- certain irreversible non-selective monoamine oxidase inhibitors (MAOIs, some used to treat depression e.g. phenelzine, moclobemide, nialamide). Irreversible, non-selective MAOIs (e.g. iproniazid) must not be used with Fluoxetine as serious or even fatal reactions (serotonin syndrome) can occur (see section 2 above “Do not take Fluoxetine”). Treatment with fluoxetine should only be started at least 2 weeks after stopping treatment with an irreversible (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 than 5 weeks may need to be considered by your doctor.
- metoprolol when used for heart failure; there is an increased risk of your heart beat becoming too slow.

Fluoxetine may affect the way the following medicines work (interaction):
- lithium, tryptophan, opioids (e.g. buprenorphine, tramadol), selegiline, the herbal remedy St. John's wort or medicines known as 'triptans' (e.g. sumatriptan, zolmitriptan - medicines for migraine). 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.
- 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 or nebivolol (for heart problems), atomoxetine (for attention-deficit hyperactivity disorder, ADHD), carbamazepine (for epilepsy), risperidone (for mental illness), tricyclic antidepressants (for example imipramine, desipramine and amitriptyline); because fluoxetine may possibly change the blood levels of these medicines.
- 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.
- medicines that affect the heart's rhythm e.g. Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazines, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobials (e.g. sparfloxacin, moxifloxacin, erythromycin given through a vein, pentamidine), antimalarial treatment particularly halofantrine, certain antihistamines used to treat allergies (astemizole, mizolastine) because taking one or more of these medicines with fluoxetine may increase the risk of changes in the electrical activity of the heart.
- mequitazine or cyproheptadine, medicines used to treat allergies.
- warfarin, NSAID or other medicines which can thin the blood (including clozapine, used to treat certain mental disorders, and aspirin); 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.
- monoamine oxidase inhibitors A (MAOI-A) including moclobemide, linezolid (an antibiotic) and methyylthioninium chloride (also called methylene blue, used for the treatment of a blood disorder (methemoglobinemia)) due to the risk of serious or even fatal reactions (called serotonin syndrome). Treatment with fluoxetine can be started the following 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 medicine.
- medicines that lower sodium levels in the blood e.g.desmopressin (used to treat certain hormone problems), oxcarbazepine (used for epilepsy), diuretics (water tablets).
- medicines that can increase the chance of seizures, such as other SSRI antidepressants (e.g. sertraline, citalopram, paroxetine), medicines for nausea and vertigo (e.g. perphenazine, prochlorperazine, chlorpromazine), certain medicines for mental illness called butyrophenones (e.g. benperidol, haloperidol), mefloquine or chloroquine (for malaria), or bupropion (for depression or nicotine dependence).

It is important that you consult your doctor or pharmacist if you are taking these or any other medicine, as he/she may need to monitor you more closely or adjust your dose.

Fluoxetine with food, drink and alcohol
- This medicine may be taken with or without food.
- Do not drink alcohol while taking this medicine.

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
In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some reports suggesting an increased risk of birth defects affecting the heart. In the general population, about 1 in100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took fluoxetine. You and your doctor may decide that it is better for you to gradually stop taking fluoxetine while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking fluoxetine.

Make sure your midwife and/or doctor know you are on 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 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/or doctor immediately.

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.

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.

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.

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
Do not drive or use machines if you feel that your abilities are affected. Medicines for the treatment of mental illnesses may decrease your ability to perform tasks requiring precision or close attention.

Fluoxetine contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Fluoxetine

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

You should swallow your capsules whole with a glass of water. This medicine may be taken with or without food.

Your doctor may need to start you on the lower strength Fluoxetine 20 mg capsules which are available.

Adults

Depression (with or without anxiety symptoms)
The recommended starting dose is 20 mg once a day. Your doctor may decide to gradually increase the dose up to a maximum of 60 mg per day.

Obsessive-compulsive disorder (OCD)
The recommended starting dose is 20 mg once a day. Your doctor may decide to gradually increase the dose up to a maximum of 60 mg per day. If no improvement is noted within 10 weeks, your doctor will reconsider your treatment.

Bulimia nervosa
The recommended dose is 60 mg daily.

Elderly
The daily dose should generally not exceed 40 mg. The maximum recommended dose is 60 mg per day.

Patients with liver problems
If you have liver problems or are using another medicine that might affect fluoxetine, your doctor may prescribe a lower dose or tell you to use fluoxetine every other day.

Use in children and adolescents aged 8 years and above
Treatment should be started and supervised by a specialist. Your specialist will prescribe the most appropriate dose.

It is very important that you follow your doctor's instructions about how many capsules to take and for how long you should continue to take them. Even when you start to feel better it is important that you keep taking them for as long as your doctor tells you to.

If you take more Fluoxetine than you should
- Contact your doctor or go to the nearest hospital casualty department immediately.
- Take the pack of capsules with you to show them.

Signs of overdose include feeling sick, being sick, fits, heart flutter or heart attack, lung problems, mental changes such as excitation or possibly coma.

If you forget to take Fluoxetine
If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, miss the forgotten dose altogether and take the next dose at the usual time. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Fluoxetine
Do not stop taking Fluoxetine until your doctor tells you to. Occasionally, side effects may occur even when treatment with fluoxetine is stopped. For this reason, when your doctor decides you should stop taking the capsules, he/she may choose to reduce the dose gradually over a number of weeks. If you experience side effects when the dose is reduced, your doctor may decide to reduce the dose more slowly.

Withdrawal symptoms
When you stop taking this medicine you may get withdrawal symptoms. This is most likely if you stop taking your medicine suddenly. Withdrawal symptoms include dizziness, tingling, numbness, difficulty in sleeping, vivid dreams, agitation, headache, tremor (shaking), feeling or being sick and anxiety. Most people find that any symptoms are mild and disappear within a few weeks but if you experience any symptoms, contact your doctor. You should not stop taking the capsules abruptly and you should discuss stopping taking this medicine with 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.

If you experience any of the following side effects, stop taking your capsules and either tell your doctor immediately or go to your nearest hospital emergency department:

Uncommon (may affect up to 1 in 100 people):
- thoughts of harming or killing yourself at any time (see section 2 'Thoughts of suicide and worsening of your depression or anxiety disorder')

Rare (may affect up to 1 in 1,000 people)
- serious allergic reactions such as severe skin rashes, red itchy swollen skin, skin sensitive to light, inflamed blood vessels (vasculitis), swelling of the face or throat, tightness of the chest, have difficulty breathing or dizziness, or have a combination of symptoms including painful joints or muscles, fever, and a rash
- fits
- changes in the electrical activity of the heart which can develop into a potentially serious heart condition known as torsades de pointes. This can result in a very fast heartbeat causing a sudden loss of consciousness
- restlessness and an inability to sit or stand still, you may have 'akathisia'
- 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)
- liver problems causing feeling or being sick, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin or whites of the eyes (jaundice), dark urine, pale stools
- skin reddening or if you develop a varied skin reaction or your skin starts to blister or peel particularly around the mouth, nose, eyes and genitals.
- a lower than normal level of sodium in the blood, which may make you feel weak and confused with aching of muscles. This may be due to inappropriate ADH secretion, a hormone that causes the body
  to retain water and dilute the blood, reducing the amount of sodium
- frequent infections with fever, chills, sore throat or mouth ulcers (reduced number of white blood cells)
- lung problems, scarring and thickening in the lungs with shortness of breath
- prolonged and painful erection

Other possible side effects

Very common (may affect more than 1 in 10 people)
- difficulties in sleeping
- headache
- feeling sick
- diarrhoea
- feeling tired or drowsy

Common (may affect up to 1 in 10 people)
- loss of appetite
- weight loss
- tiredness
- sleepiness
- feeling anxious or nervous
- restlessness
- difficulty concentrating
- feeling tense

- decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity) abnormal or vivid dreams
- feeling dizzy
- changes in taste
- shaking
- blurred vision
- rapid and irregular heartbeat sensations
- other changes to the electrical activity of the heart called QT prolongation, which can be seen on an ECG, an electrical recording of the heart).
- feeling flushed
- yawning
- indigestion
- vomiting
- dry mouth
- rash, urticaria, itching
- excessive sweating,
- joint pain
- passing urine more frequently
- unexplained vaginal bleeding
- feeling shaky or chills

Uncommon (may affect up to 1 in 100 people)
- mood changes
- feeling detached
- strange thinking
- memory problems
- feel high (euphoria)
- inability to orgasm
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or coordination
- enlarged (dilated) pupils
- low blood pressure
- shortness of breath
- swallowing problems
- abdominal bleeding
- ringing in the ears
- nose bleeds
- hair loss
- increased tendency to bruising
- cold sweat
- pain when passing urine
- feeling hot or cold
- generally feeling unwell/abnormal
- increase in liver enzymes seen in a blood test

Rare (may affect up to 1 in 1,000 people)
- low levels of salt in the blood
- untypical wild behaviour
- hallucinations (see, hear or feel things that are not there)
- feel agitated
- panic attacks
- confusion
- aggression
- stuttering or stammering
- widening of blood vessels

- pain in the tube that takes food or water to your stomach
- sensitivity to sunlight
- leaking of milk from the breast
- sore throat and discomfort when swallowing
- aching muscles, muscle tenderness or weakness, not caused by exercise
- difficulty passing urine
- unusual bleeding or bruising, frequent infections with fever, chills, sore throat or mouth ulcers (reduced number of white blood cells)
- high prolactin levels in the blood
- bleeding from the mucosal lining of areas such as the mouth and nose

Not known (frequency cannot be estimated from the available data)
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding, fertility in section 2 for more information

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

Additional side effects in children and adolescents (8-18 years): Fluoxetine may slow growth or possibly delay sexual maturity. Other behavioural changes may be seen such as: anger, mood change or disorder, aggression and anxiety. Nose bleeds were also commonly reported in children.

Reporting 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 at: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Fluoxetine

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 or blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 contains

- The active substance is fluoxetine (as fluoxetine hydrochloride)
- The other ingredients are lactose monohydrate, maize starch, colloidal anhydrous silica, talc, magnesium stearate, gelatin, titanium dioxide (E171), yellow iron oxide (E172), shellac, potassium hydroxide, ammonium hydroxide and iron oxide black (E172). See section 2 'Fluoxetine contains lactose'.

What Fluoxetine looks like and contents of the pack

Your medicine is a hard capsule with a light-yellow, opaque body and cap printed "FL60" on the body and "G" on the cap.

Your medicine is available in blisters packs of 30 capsules.

Marketing Authorisation Holder

Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Mylan Hungary Kft., Mylan utca 1., Komárom, 2900, Hungary

This leaflet was last revised in 10/2026