Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Fluoxetine Capsules are and what they are used for.
2. Before you take Fluoxetine Capsules
3. How to take Fluoxetine Capsules
4. Possible side effects
5. How to store Fluoxetine Capsules
6. Further 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)
- Bulimia nervosa: for the reduction of binge-eating and purging activity

2. 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 and tell your doctor if:

- You are allergic (hypersensitive) 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.
- You are taking medicines that thin the blood (anti-coagulants) since these medicines all take time to work, the symptoms of obsessive-compulsive disorder (OCD), bulimia nervosa: for the reduction of binge-eating and purging activity
- You have a family history of allergic reactions to fluoxetine capsules (including fluoxetine hydrochloride or any of the other ingredients listed in Section 6).

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

However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide).

Do not take any 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.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines take time to work. You usually work for about 2 weeks but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts about harming or killing 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.

Take special care with fluoxetine and tell your doctor if:

- have epilepsy or fits (séances) or experience seizures 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
- are taking medicines that thin the blood (see ‘Taking other medicines’)
- are having ECT (electro-convulsive therapy) treatment
- have a history of bleeding disorders or you develop bruises or unusual bleeding reactions can occur. Examples of MAOIs include nialamide, iproniazide, selegiline, moclobemide, tranylcypromine, isocarboxazid and tolcapone.

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

Adults:
The usual 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 dosage 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 symptoms may not occur until after the first 2 to 4 weeks of treatment. Patients with depression should be treated for at least 3 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.

Children and adolescents:
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 medicines that might affect liver function, 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 should take too much medicine, contact your doctor or nearest hospital emergency department immediately.

Always take any medicine left over with and also the box, as this will allow easier identification of the medication.

If you forget to take fluoxetine:
If you forget to take a dose, simply take the next dose when it is due. Never take an extra 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 when you stop taking fluoxetine: dizziness; tingling feelings like pins and needles; sleep disturbances (wild dreams); feeling unwell; inability to sleep; feeling restless or agitated; unusual tiredness or weakness; feeling anxious or depressed; feeling sick; twitching (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.
- If you get a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath.
- If you feel restless and cannot sit or stand still, you may have akathisia, increasing your dose may make you feel worse.
- 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.

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 sleeplessness (only rarely).
- feeling weak or tired.
- inability to sleep; feeling restless or agitated; disturbances (vivid dreams, nightmares, or bad dreams); headache.Taking diuretics (water tablets);
- prolonged and painful erection;
- irritability and extreme agitation.

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

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 (seen in more than 1 in every 10 patients):
- insomnia
- headache
- difficulty sleeping, feeling sick (nausea)
- fatigue

Common (seen in 1 to 10 in every 100 patients):
- not feeling hungry, weight loss
- nervousness, anxiety
- restlessness, poor concentration
- feeling tense
- disturbed sex drive or sexual problems (including difficulty maintaining an erection for sexual activity)
- sleep problems, unusual dreams, tiredness or sleepiness
- dizziness
- change in taste
- uncontrollable shaking movements
- blurred vision
- rapid and irregular heartbeat sensations
- flushing
- indigestion, vomiting
- dry mouth
- rash, itchy skin, itching
- excessive sweating
- joint pain
- passing urine more frequently
- unexplained vaginal bleeding
- feeling shaky or chilly

Uncommon (seen in 1 in 10 to in every 1,000 patients):
- feeling detached from yourself or strange thinking
- abnormally high mood
- organ system (nervous system)
- muscle twitching, involuntary movements or problems with balance or co-ordination
- dilated pupils
- low blood pressure
- shortness of breath
- difficulty swallowing
- hallucinations
- increased tendency to bruising
- cold sweat
- difficulty passing urine
- feeling hot or cold

Rare (seen in 1 in 10 to in every 10,000 patients):
- low levels of salt in the blood
- unusual wild behaviour
- hallucinations
- agitation
- panic attacks
- chest pains
- vasculitis (inflammation of a blood vessel)
- rapid swelling of the tissues around the face, mouth and/or throat
- pain in the tube that takes food or water to your stomach
- sensitivity to sunlight
- producing breast milk

Other (frequency cannot be estimated):
- thoughts of suicide or harming yourself
- lung problems
- hepatitis, abnormal liver function test results
- muscle pain
- problems urinating
- confusion
- nose bleeds
- unexplained bruising or bleeding

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 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 CAPSULES

• Keep out of the reach and sight 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 light.
• Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 lauryl sulfate, yellow iron oxide (E172), titanium dioxide (E127) and black edible printing ink, which contains dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, iron oxide, titanium dioxide (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 August 2017.

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