Package leaflet: Information for the user

Fluoxetine 20mg Hard Capsules

Fluoxetine

Eight important things you need to know about Fluoxetine capsules

- **Fluoxetine treats depression and anxiety disorders.** Like all medicines, it can have unwanted effects. It is therefore important that you and your doctor weight up the benefits of treatment against the possible unwanted effects, before starting treatment.
- **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 haven't started feeling better. See section 3, How to take Fluoxetine capsules.
- **Fluoxetine is not for use in children and adolescents under 18.** See Section 2, *Use in children & adolescents aged 8 to 18 years*.
- **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 Fluoxetine without talking to your doctor.** If you stop taking Fluoxetine 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 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, *Taking other medicines*.
- **If you are pregnant or planning to get 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 capsule is and what it is 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 Capsule is and what it is used for

Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) antidepressant that influences the central nervous system.

Fluoxetine is used for the treatment of:

Adults:

- Major depressive episodes
- Obsessive thoughts and obsessive actions
- Bulimia Nervosa: Fluoxetine capsule is used alongside psychotherapy for the reduction of binge eating and purging.

Children and adolescents aged 8 years and above:

- Moderate to severe major depressive disorder, if the depression does not respond to psychological therapy after 4-6 sessions. Fluoxetine capsules should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy.

Note that the doctor may have prescribed this medicine for a different purpose and/or at a different dosage from that given in the package leaflet. You must always follow the doctor's prescription and the instructions given on the label of the pack.

How Fluoxetine 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

Do not take Fluoxetine Capsules :

- If you have had any allergic reaction to fluoxetine or to any of the other ingredients in the product (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 other medicines known as irreversible, non-selective monoamine oxidase inhibitors (MAOIs), since serious or even fatal reactions can occur (e.g. tranylcypromine).

Treatment with Fluoxetine Capsules should only be started 2 weeks after discontinuation of an irreversible MAOI. Do not take any irreversible non selective MAOIs for at least 5 weeks after you stop taking Fluoxetine capsules. If Fluoxetine capsules has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor

- 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 or pharmacist before taking Fluoxetine capsules if any of the following applies to you:

- Heart problems;
- appearance of 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** since Fluoxetine capsules might need to be discontinued;
- mania now or in the past; if you have a manic episode, **contact your doctor immediately** because Fluoxetine capsules might need to be discontinued;
- history of bleeding disorders or appearance of bruises or unusual bleeding;
- ongoing treatment with medicines that thin the blood (see "Other medicines and Fluoxetine capsules);
- epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, **contact your doctor immediately**; Fluoxetine capsules might need to be discontinued;
- ongoing ECT (electroconvulsive therapy);
- ongoing treatment with tamoxifen (used to treat breast cancer) (see "Other medicines and Fluoxetine capsules');
- starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Fluoxetine capsules may make this worse;
- diabetes (your doctor may need to adjust your dose of insulin or other antidiabetic treatment);
- liver problems (your doctor may need to adjust your dosage);
- 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);
- ongoing treatment with diuretics (water tablets), especially if you are elderly;
- *glaucoma (increased pressure in the eye);*

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 anxiely 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 aged 8 to 18 years of age

Patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Fluoxetine Capsule 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) and it should not be used to treat other conditions.

Additionally, only limited information concerning the long-term safety of Fluoxetine Capsules on growth, puberty, mental, emotional and behavioural development in this age group is available. Despite this, and if you are a patient under 18, your doctor may prescribe Fluoxetine Capsule for moderate to severe major depressive episodes in combination with psychological therapy because, he/she decides that this is in your best interests. If your doctor has prescribed Fluoxetine Capsules for a patient under 18 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 are taking Fluoxetine Capsules.

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

Other medicines and Fluoxetine Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Donot take Fluoxetine capsule with:

- **Certain irreversible non selective monoamine oxidase inhibitors (MAOIs)**, some used to treat depression. Irreversible non selective MAOIs must not be used with Fluoxetine capsules as serious or even fatal reactions (serotonin syndrome) can occur (see section "Do not take Fluoxetine capsules"). Treatment with Fluoxetine capsules should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI (for instance tranylcypromine). Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking Fluoxetine capsules. If Fluoxetine capsules 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 capsules may affect the way the following medicines work (interaction);

- **Tamoxifen** (used to treat breast cancer); because Fluoxetine capsule may change the blood levels of this drug, resulting in the possibility of a reduction in the effect of tamoxifen, your doctor may need to consider prescribing a different antidepressant treatment.
- **monoamine oxidase inhibitor A (MAOI-A)** including moclobemide, linezolid (an antibiotic) and methylthioninium chloride (also called methylene blue used to <indication(s) authorised in member state>); 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.

- **Mequitazine** (for allergies); because taking this drug with Fluoxetine capsule may increase the risk of changes in the electrical activity of the heart.
- **Phenytoin** (for epilepsy); because Fluoxetine capsule 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 capsule.
- **lithium, selegiline, St. John's Wort, Tramadol** (a painkiller), **triptans** (for migraine) and **tryptophan**; there is an increased risk of mild serotonin syndrome when these drugs are taken with Fluoxetine capsule. 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 capsule may increase the risk of changes in the electrical activity of the heart.
- **Anti-coagulants** (such as warfarin), **NSAID** (such as ibruprofen, diclofenac), **aspirin** and **other medicines which can thin the blood** (including clozapine, used to treat certain mental disorders); Fluoxetine capsule may alter the effect of these medicines on the blood. If Fluoxetine capsules 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 capsule.
- **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 capsule.
- **anti-depresants** such as tricyclic anti-depressants, other selective serotonin reuptake inhibitors (SSRIs) or **bupropion, mefloquine or chloroquine** (used to treat malaria), **tramadol** (used to treat severe pain) or **anti-psychotics** such as phenothiazines or butyrophenones ; because Fluoxetine capsule may increase the risk of seizures when taken with these medicines.
- **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 capsules may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Fluoxetine capsule.

Fluoxetine Capsule with food, drink and alcohol

Food:
The capsules may be taken with or between meals.

Alcohol:
The combination of Fluoxetine capsules and alcohol is not recommended.

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
Talk to your doctor as soon as possible if you're pregnant, if you might be pregnant, or if you're planning to become pregnant.

In babies whose mothers took Fluoxetine capsules 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 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took Fluoxetine capsules. You and your doctor may decide that it is better for you to gradually stop taking Fluoxetine capsules while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Fluoxetine capsules.

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

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
Fluoxetine capsules can impair judgement, thinking capacity and motor skills. This should be taken into account in situations where increased alertness is necessary, e.g. when driving or operating hazardous machinery.

3. How to take Fluoxetine capsules

Always take Fluoxetine capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the capsules with a drink of water. Do not chew the capsules

Adults:
The recommended dose is:

- **Depression:** The recommended dose is 1 capsule (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 3 capsules (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 3 capsules (60 mg) daily.
- **Obsessive-compulsive disorder (OCD):** The recommended dose is 1 capsule (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 3 capsules (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:
Treatment should be started and be supervised by a specialist.

The starting dose is 10mg/day.

After 1 to 2 weeks, your doctor may increase the dose to 20mg/day. The dose should be increased carefully to ensure that you receive the lowest effective dose. Lower weight children may need lower doses. If there is a satisfactory response to treatment, your doctor will review the need for continuing treatment beyond 6 months. If you have not improved within 9 weeks, your doctor will reassess your treatment.

Elderly:
Your doctor will increase the dose with more caution and the daily dose should generally not exceed 2 capsules (40 mg).

The maximum dose is 3 capsules (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 capsules than you should

- If you take too many capsules, go to your nearest hospital emergency department (or casualty) or tell your doctor straight away.
- Take the pack of Fluoxetine capsules with you if you can.

Symptoms of overdose: nausea, vomiting, seizures, heart problems (like irregular heart beat and cardiac arrest), lung problems and change in mental condition ranging from agitation to coma.

If you forget to take Fluoxetine capsules
If you miss a dose, do not worry. Take your next dose the next day at the usual time. Do not take a double dose to make up for a forgotten dose.
Taking your medicine at the same time each day may help you to remember to take it regularly.

If you stop taking Fluoxetine capsules

- Do not stop taking Fluoxetine capsules 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 capsules: 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 capsules are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor. When stopping Fluoxetine capsules, 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 product, 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 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 of Fluoxetine capsules 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.

The most frequent sides effects (very common side effects that may affect more than 1 user in 10) are insomnia, headache, diarrhoea, feeling sick (nausea) and fatigue.

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.

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

The following side effects have also been reported in patients taking Fluoxetine capsules:

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
- 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
- unexplained vaginal bleeding
- feeling shaky or chills

Uncommon (may affect up to 1 in 100 people)

- feeling detached from yourself
- strange thinking
- abnormally high mood
- orgasm problems
- thoughts of suicide or harming yourself
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or co-ordination
- memory impairment
- enlarged (dilated) pupils
- ringing in the ears
- low blood pressure
- shortness of breath
- nose bleeds
- difficulty swallowing
- hair loss
- increased tendency to bruising
- unexplained bruising or bleeding
- cold sweat
- difficulty passing urine
- feeling hot or cold
- abnormal liver function test results

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

- low levels of salt in the blood
- reduction in blood platelets, which increases risk of bleeding or bruising
- reduction in white blood cell count
- unpyical wild behaviour
- hallucinations
- agitation
- panic attacks
- confusion
- stuttering
- aggression
- fits
- 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
- hepatitis
- lung problems
- sensitivity to sunlight
- muscle pain
- problems urinating
- producing breast milk

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

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

In Children and Adolescents (8-18 years)

In addition to the possible side effects listed above, Fluoxetine capsules may slow growth or possibly delay sexual maturity. Suicide-related behaviours (suicide attempt and suicidal thoughts), hostility, mania, and nose bleeds were also commonly reported in children.

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 website: 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 sight and reach of children.

Do not store above 25º C.
Store in the original package in order to protect from moisture.

Do not use Fluoxetine capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month

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 20mg contains
The active substance is fluoxetine hydrochloride equivalent to 20 mg fluoxetine.
The other ingredient is pre-gelatinised maize starch.
The capsule shell contains gelatine, brilliant blue (E133), titanium dioxide (E171), yellow iron oxide (E172). Printing ink components are activated charcoal and shellac (E904).

What Fluoxetine capsules 20mg look like and contents of the pack
Fluoxetine 20 mg capsules are green/off white gelatine capsules with FLX/MIL marked on it and available in blister packs of 10, 14, 20, 30, 50, 70 or 100 capsules.
Not all pack sizes may be marketed

Marketing Authorisation Holder
Brown & Burk UK Ltd
5, Marryat Close, Hounslow west,
Middlesex TW4 5DQ, UK

Site responsible for batch release
Brown & Burk UK Ltd
5, Marryat Close, Hounslow west,
Middlesex TW4 5DQ, UK

This leaflet was last approved in 04/2016

PL20016/AB UKI-0332A