

PATIENT INFORMATION LEAFLET
Fluoxetine 20 mg/5 ml Oral Solution
Fluoxetine hydrochloride

Important things that you need to know about Fluoxetine

- Your doctor has prescribed Fluoxetine because it is a treatment for depression, bulimia nervosa or obsessive compulsive disorders.
- Fluoxetine won't work straight away. Some people taking antidepressants feel worse before feeling better. Your doctor should see you regularly during your course of treatment. Tell your doctor if you haven't started feeling better.
- If you are pregnant or could get pregnant you should talk to your doctor before taking Fluoxetine. See section 2.
- Taking other medicines with Fluoxetine can cause problems. You may need to talk to your doctor. See section 2.
- 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 hospital straight away.

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 doctor.
- 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.

In this leaflet:

- What Fluoxetine is and what it is used for
- Before you take Fluoxetine
- How to take Fluoxetine
- Possible side effects
- How to store Fluoxetine
- Further information

1. WHAT FLUOXETINE IS AND WHAT IT IS USED FOR

Fluoxetine belongs to a group of medicines called antidepressants. It is used to treat the following conditions:

Adults:

- major depressive episodes
- obsessive compulsive disorder
- bulimia nervosa

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 should be offered to a child or young person with moderate to severe major depressive disorder **only** in combination with psychological therapy.

2. BEFORE YOU TAKE FLUOXETINE

Do not take Fluoxetine if you

- are allergic (hypersensitive) to fluoxetine or any of the other ingredients of Fluoxetine (see Section 6 and end of Section 2).
- are taking metoprolol which is used to treat cardiac failure.
- are already taking monoamine oxidase inhibitors (MAOIs) or you have finished taking a course of them in the last two weeks. Examples of such MAOIs include medicines used to treat depression such as nialamide, iproniazide, moccobemide, phenelzine, tranylcypromine, isocarboxazid, toloxatone and also linezolid (an antibiotic).

Treatment with fluoxetine should only be started at least 2 weeks after discontinuation of an irreversible non-selective MAOI. However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs for e.g. moclobemide, linezolid, methylthionium (methylene blue). Do not take MAOI's for at least 5 weeks after you stop taking fluoxetine.

Take special care with Fluoxetine and tell your doctor if you have:

- a fit (seizures) or experience an increase in seizure frequency, contact your doctor immediately; fluoxetine might need to be discontinued.
- liver or kidney problems. A low dose of Fluoxetine may be appropriate for you.
- diabetes, as your dose may need to be adjusted, as Fluoxetine contains sucrose.
- ever had mania or its mild form (hypomania).
- heart problems.
- low resting heart-rate and/or if you know that you may have salt depletion as a result of prolonged diarrhoea or vomiting, or use of diuretics.
- History of bleeding disorders, bleeding or blood clotting problems which may be controlled by medicine, or if you are pregnant (see 'Pregnancy').
- are taking medicines that thin the blood.
- begun 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.
- a rare hereditary fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
- alcoholism. You must not consume alcohol while taking Fluoxetine.
- are undergoing ECT (electro-convulsive therapy).
- are being treated with tamoxifen (used to treat breast cancer) (see Taking other medicines).
- start to feel restless and cannot sit or stand still (akathisia). Increasing your dose of fluoxetine may make this worse.
- suffer withdrawal symptoms (see Taking other medicines).
- Glaucoma (increased pressure in the eye).
- are taking Irreversible non selective MAOI's (see section 2).

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 yourself. These thoughts may increase when first taking fluoxetine, 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 or if you are a young adult, as clinical trials have shown an increased risk of suicidal behaviour in adults 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 straight to a hospital. You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, ask them to read this leaflet. You should also ask them to tell you if they notice that your depression or anxiety is getting worse or if they are worried about changes in your behaviour.

Children and adolescents aged 8 to 18 years

Patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominantly aggression, oppositional behaviours and anger) when they take 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) and it should not be used to treat other conditions. Additionally, 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 this medicine because he/she decides it is in your best interest.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines (up to 5 weeks ago), including medicines obtained without a prescription.

Fluoxetine may affect the way some medicines work, especially the following:

- monoamine oxidase inhibitors (MAOIs) which are used to treat depression. Irreversible nonselective MAOIs must not be used with fluoxetine as serious fatal reactions (serotonin syndrome) can occur (see section Do not take fluoxetine). Some MAOIs type A for example moclobemide, linezolid, methylthionium chloride (methylene blue) type B (selegiline) can be used with fluoxetine provided that your doctor monitors you closely.
- metoprolol (which is used to treat heart problems).
- tamoxifen (which is used to treat breast cancer).
- alcohol.
- mequitazine (which is used to treat allergies and rhinitis).
- phenytoin (for epilepsy)
- medicines that increase the level of serotonin such as lithium, tramadol (a painkiller), triptans (for migraine), tryptophan, selegiline or St. John's Wort.
- 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, certain antihistamines (astemizole and mizolastine).
- medicines affecting CYP2D6 enzyme such as flecainide, propafenone and nebivol (for heart problems), carbamazepine (for epilepsy), tricyclic antidepressants (for example imipramine, desipramine and amitriptyline), atomoxetine (for attention deficit and hyperactivity disorders) and risperidone (for some psychiatric disorders).
- cyproheptadine (for treating allergic reactions).
- warfarin (used to thin your blood).
- diuretics (water tablets that help you pass more urine), especially if you are elderly.
- 'atypical antipsychotics' (like clozapine, phenothiazines).
- NSAIDs such as aspirin or ibuprofen.

Taking Fluoxetine with food and drink

You may take Fluoxetine with or without food. You must not drink alcohol while 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

Talk to your doctor as soon as possible if you are pregnant, if you might be pregnant or if you are planning to become pregnant. In babies whose mothers took fluoxetine during the first few months of pregnancy, studies have described an increased risk of birth defects affecting the heart. The increase was from 1 in 100 babies in the general population to 2 in 100 where the mother took fluoxetine. In babies whose mothers took fluoxetine during pregnancy, particularly the last three months of pregnancy there is an increased risk of a condition called persistent pulmonary hypertension (PPHN), which makes 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 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. You and your doctor may decide to gradually stop taking fluoxetine while you are pregnant or before becoming pregnant. However, depending on the circumstances, your doctor may suggest that it is better for you to keep taking this medicine. Caution should be exercised when used during pregnancy especially during late pregnancy and just before giving birth since the following effects have been reported in new born babies, irritability, tremor, muscle weakness, persistent crying and difficulty sucking or sleeping.

¹ 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.

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 should not cause drowsiness or dizziness, but do not drive or operate machinery without advice from your doctor or pharmacist.

Important information about some of the ingredients of Fluoxetine

Fluoxetine contains:

- Ethanol:** Each 5 ml of Fluoxetine contains small amounts of ethanol (alcohol), but less than 100 mg per dose.
- Sucrose:** Each 5 ml of Fluoxetine contains 3 g of sucrose. If taken according to the dosing recommendations, it can supply up to 12 g of sucrose daily. If you have an intolerance to some sugars (which may be inherited), contact your doctor before taking this medicinal product. This should also be taken into account if you have diabetes mellitus.

3. HOW TO TAKE FLUOXETINE

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

The usual dose to be taken by mouth is:

| For Adults and the Elderly: | |
|---|--|
| Depression: | 20 mg (one 5 ml spoonful) per day. The daily dose must not exceed 80 mg per day. |
| Bulimia nervosa: | 60 mg (three 5 ml spoonfuls) per day. |
| Obsessive compulsive disorder: | 20 – 60 mg (one to three 5 ml spoonfuls). |
| For Children and Adolescents | |
| aged 8 to 18 years with depression: | Treatment should be started and be supervised by a specialist. The starting dose is 10 mg/day (given as 2.5 ml of Fluoxetine). After 1 to 2 weeks, your doctor may increase the dose to 20 mg/day. The dose should be increased to ensure that you receive the lowest effective dose. Lower weight children may need lower doses. Your doctor will review the need for continuing treatment beyond 6 months, and treatment will be reassessed if no improvement is seen. |
| For Children under the age of 8 years: | Not recommended. |

If you have kidney or liver problems, your doctor may prescribe reduced or less frequent doses for you.

If you take more Fluoxetine than you should

If you have taken more Fluoxetine than you should, contact your doctor, pharmacist or nearest hospital casualty department **immediately**. Symptoms of overdose include nausea, vomiting, fits, heart problems (including irregular heart beat and cardiac arrest) lung problems and change in mental condition ranging from agitation to coma.

If you forget to take Fluoxetine

If you miss a dose, **DO NOT** take a double dose to make up for the forgotten dose, just take your next dose of Fluoxetine at your next dosage time.

If you stop taking Fluoxetine

If you are prescribed other medicines within 5 weeks of stopping your treatment, tell your doctor or pharmacist that you have been taking Fluoxetine. Common withdrawal symptoms are: dizziness, headache, pins and needles, anxiety, feeling sick, sleep disturbances, feeling restless or agitated, unusual tiredness or weakness and tremors (shakiness).

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

4. POSSIBLE SIDE EFFECTS

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

Cases of suicidal ideation and suicidal behaviours have been reported during Fluoxetine therapy or early after treatment discontinuation.

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.

You should STOP using Fluoxetine and contact your doctor immediately if you experience a rare allergic reaction, including swelling of the skin and rashes, difficulty breathing, loss of consciousness, and fever or shock.

Contact your doctor if you experience the following:

- fever accompanied by faster breathing, sweating, muscle stiffness or sleepiness.

The following side-effects have also been reported in patients taking fluoxetine:

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

- difficulty sleeping
- headache
- diarrhoea, feeling sick
- tiredness

Common (may affect up to 1 in 10 people)

- not feeling hungry, weight loss
- feeling more nervous than usual, feeling anxious
- sleep problems, unusual dreams, tiredness or sleepiness
- change in the way things taste
- blurred vision
- flushing
- Indigestion, being sick
- itchy, lumpy rash (hives) or nettle rash (urticaria), itching
- joint pain
- feeling shaky or chills
- decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity)

- restlessness, poor concentration
- feeling tense
- dizziness
- uncontrollable shaking
- hair loss
- rapid and irregular heartbeat sensations
- yawning
- dry mouth
- excessive sweating
- passing urine more frequently
- unexplained vaginal bleeding

Uncommon (may affect up to 1 in 100 people)

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

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

- reduction in blood platelets which increases risk of bleeding or bruising
- low levels of salt in the blood
- low levels of certain types of white blood cells
- overactive behaviour or thoughts
- seeing or hearing things that are not there
- agitation
- finding it difficult to breathe
- fits
- rapid swelling of the tissues around the neck, face, mouth and/or throat
- inflammation of a blood vessel
- pain in the tube that takes food or water to your stomach
- you become more sensitive to the sun than usual
- producing breast milk
- sore throat
- confusion
- stuttering
- aggression
- lung problems
- hepatitis
- muscle pain
- problems passing urine
- psychomotor restlessness
- involuntary movements of the body
- severe skin reaction, known as Steven Johnsons syndrome

Not Known (frequency cannot be estimated from the available data)

- burning pain and redness of the skin
- feeling dizzy or light-headed when you stand or sit up quickly
- reduced sense of touch
- difficulty in making voice sounds
- burning, tingling mouth
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy' in section 2 for more information.

Risk of bone fractures

An increased risk of bone fractures has been observed in patients taking this type of medicine. Most of these side effects are likely to disappear with discontinued treatment. In children and adolescents (8 -18 years) – In addition to the possible side effects listed above, fluoxetine may slow growth or possibly delay sexual maturity. 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUOXETINE

Keep out of the sight and reach of children. Do not store above 25°C. Store in the original container. Once opened, use within 1 month. Do not use Fluoxetine after the expiry date which is stated on the label or 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 contains:

- The **active substance** is: fluoxetine hydrochloride; each 5 ml contains 20 mg fluoxetine
- The **other ingredients** are: sucrose, glycerol (E422), peppermint soluble, ethanol, benzoic acid (E210), hydrochloric acid, sodium hydroxide, purified water.

What Fluoxetine looks like and contents of the pack

- Fluoxetine is a clear colourless solution with a peppermint odour, and is available in 70 ml amber glass bottles.

Marketing Authorisation Holder:

Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland.

Manufacturer:

Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland or
CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF, United Kingdom.

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