

PROZAC PRODUCT INFORMATION LEAFLET

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:

1. What Fluoxetine is and what it is used for
2. Before you take Fluoxetine
3. How to take Fluoxetine
4. Possible side effects
5. How to store Fluoxetine
6. 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, modobemide, phenelzine, tranylcypromine, isocarboxazid, tolaxatone 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 sugar.

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 coordination