Medication Guide

Fluoxetine Oral **S**olution, USP
(floo ox' e teen)

Read the Medication Guide that comes with fluoxetine before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or you want to learn more about fluoxetine.

What is the most important information I should know about fluoxetine?

Fluoxetine and other antidepressant medicines may cause serious side effects, including:

1. **Suicidal thoughts or actions:**
   - **Fluoxetine and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults within the **first few months of treatment or when the dose is changed.**
   - Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
   - Watch for these changes and call your healthcare provider right away if you notice:
     - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
     - Pay particular attention to such changes when fluoxetine is started or when the dose is changed.

   Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. Fluoxetine may be associated with these serious side effects:

2. **Serotonin Syndrome. This condition can be life-threatening and may include:**
   - agitation, hallucinations, coma or other changes in mental status
   - coordination problems or muscle twitching (overactive reflexes)
   - racing heartbeat, high or low blood pressure
   - sweating or fever
   - nausea, vomiting, or diarrhea
   - muscle rigidity
   - dizziness
   - flushing
   - tremor

- seizures

3. **Severe allergic reactions:**
   - trouble breathing
   - swelling of the face, tongue, eyes or mouth
   - rash, itchy welts (hives) or blisters, alone or with fever or joint pain

4. **Abnormal bleeding:** Fluoxetine and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin®, Jantoven®), a non-steroidal anti-inflammatory drug (NSAIDs, like ibuprofen or naproxen), or aspirin.

5. **Visual Problems:**
   - eye pain
   - changes in vision
   - swelling or redness in or around the eye

6. **Seizures or convulsions**

7. **Manic episodes:**
   - greatly increased energy
   - severe trouble sleeping
   - racing thoughts
   - reckless behavior
   - unusually grand ideas
   - excessive happiness or irritability
   - talking more or faster than usual

8. **Changes in weight or appetite.** Children and adolescents should have height and weight monitored during treatment.

9. **Low salt (sodium) levels in the blood.** Elderly people may be at greater risk for this. Symptoms may include:
   - headache
   - weakness or feeling unsteady
   - confusion, problems concentrating or thinking or memory problems

10. **Changes in the electrical activity of your heart (QT prolongation and ventricular arrhythmia including Torsades de Pointes). This condition can be life threatening. The symptoms may include:**
    - fast, slow, or irregular heartbeat
    - shortness of breath
    - dizziness or fainting

11. **Sexual problems (dysfunction).** Taking selective serotonin reuptake inhibitors (SSRIs), including fluoxetine, may cause sexual problems.

    Symptoms in males may include:
    - Delayed ejaculation or inability to have an ejaculation
    - Decreased sex drive
    - Problems getting or keeping an erection

    Symptoms in females may include:
    - Decreased sex drive
    - Delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with fluoxetine. There may be treatments your healthcare provider can suggest.

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

Do not stop fluoxetine without first talking to your healthcare provider. Stopping fluoxetine too quickly may cause serious symptoms including:

- anxiety, irritability, high or low mood, feeling restless or changes in sleep habits
- headache, sweating, nausea, dizziness
- electric shock-like sensations, shaking, confusion

What is fluoxetine?

Fluoxetine is a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider.

Fluoxetine is used to treat:

- Major Depressive Disorder (MDD)
- Obsessive Compulsive Disorder (OCD)
- Bulimia Nervosa*
- Panic Disorder*

*Not approved for use in children

Talk to your healthcare provider if you do not think that your condition is getting better with fluoxetine treatment.

Who should not take fluoxetine?

Do not take fluoxetine if you:

- are allergic to fluoxetine hydrochloride or any of the ingredients in fluoxetine hydrochloride oral solution. See the end of this Medication Guide for a complete list of ingredients in fluoxetine hydrochloride oral solution.
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
    - Do not take an MAOI within 5 weeks of stopping fluoxetine unless directed to do so by your physician.
    - Do not start fluoxetine if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take fluoxetine close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- high fever
- uncontrolled muscle spasms
- stiff muscles
- rapid changes in heart rate or blood pressure
- confusion
- loss of consciousness (pass out)

- **take Mellaril® (thioridazine). Do not take Mellaril® within 5 weeks of stopping fluoxetine because this can cause serious heart rhythm problems or sudden death.**
- **take the antipsychotic medicine pimozide (Orap®) because this can cause serious heart problems.**

What should I tell my healthcare provider before taking fluoxetine?
Ask if you are not sure.

Before starting fluoxetine, tell your healthcare provider if you:

- Are taking certain drugs or treatments such as:
  - Triptans used to treat migraine headache
  - Medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, buspirone, SSRIs, SNRIs, MAOIs or antipsychotics
  - amphetamines
  - Tramadol and fentanyl
  - Or other opioids
  - Over-the-counter supplements such as tryptophan or St. John's Wort
- Electroconvulsive therapy (ECT)
- have liver problems
- have kidney problems
- have heart problems
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have a history of a stroke
- have high blood pressure
- have or had bleeding problems
- are pregnant or plan to become pregnant. It is not known if fluoxetine will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy.
- are breast-feeding or plan to breast-feed. Fluoxetine may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking fluoxetine.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Fluoxetine and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Your healthcare provider or pharmacist can tell you if it is safe to take fluoxetine with your other medicines. Do not start or stop any medicine while taking fluoxetine without talking to your healthcare provider first.

If you take fluoxetine, you should not take any other medicines that contain fluoxetine hydrochloride including:

- *Symbyax®
- *Sarafem®
- *PROZAC® Weekly.

How should I take fluoxetine?

- Take fluoxetine exactly as prescribed. Your healthcare provider may need to change the dose of fluoxetine until it is the right dose for you.
- Fluoxetine may be taken with or without food.
- If you miss a dose of fluoxetine, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of fluoxetine at the same time.
- If you take too much fluoxetine, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking fluoxetine?

Fluoxetine can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how fluoxetine affects you. Do not drink alcohol while using fluoxetine.

What are the possible side effects of fluoxetine?

Fluoxetine may cause serious side effects, including:

- See "What is the most important information I should know about fluoxetine?"
- **Problems with blood sugar control.** People who have diabetes and take fluoxetine may have problems with low blood sugar while taking fluoxetine. High blood sugar can happen when fluoxetine is stopped. Your healthcare provider may need to change the dose of your diabetes medicines when you start or stop taking fluoxetine.
- **Feeling anxious or trouble sleeping**

Common possible side effects in people who take fluoxetine include:

- unusual dreams
- sexual problems
- loss of appetite, diarrhea, indigestion, nausea or vomiting, weakness, or dry mouth
- flu symptoms
- feeling tired or fatigued
- change in sleep habits
- yawning
- sinus infection or sore throat
- tremor or shaking
- sweating
- feeling anxious or nervous
- hot flashes
- rash

Other side effects in children and adolescents include:

- increased thirst
- abnormal increase in muscle movement or agitation
- nose bleed
- urinating more often
- heavy menstrual periods
- possible slowed growth rate and weight change. Your child's height and weight should be monitored during treatment with fluoxetine.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of fluoxetine. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088.

How should I store fluoxetine?

- Store fluoxetine at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
- Keep fluoxetine away from light.
- Keep fluoxetine bottle closed tightly.

Keep fluoxetine and all medicines out of the reach of children.

General information about fluoxetine

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use fluoxetine for a condition for which it was not prescribed. Do not give fluoxetine to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about fluoxetine. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about fluoxetine that is written for healthcare professionals.

For more information about fluoxetine call 1-845-232-1683.

What are the ingredients in fluoxetine?

Active ingredients: fluoxetine hydrochloride
Inactive ingredients in oral solution: benzoic acid, sucrose, glycerin, peppermint flavor, and purified water.

Manufactured for:
Chartwell RX, LLC.
Congers, NY 10920

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