**Medication Guide**

**FLUOXETINE (flo ox' e teen) CAPSULES USP**

Read the Medication Guide that comes with fluoxetine capsules 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 want to learn more about.

**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.

2. **Serotonin Syndrome.** This condition can be life-threatening and may occur with these serious side effects:
   - Loss of consciousness (pass out)
   - Confusion
   - Rapid changes in heart rate or blood pressure
   - Uncontrolled muscle spasms
   - Headache
   - Sweating or fever
   - Rash, hives, or blisters, alone or with fever or joint pain
   - Rapid changes in heart rate or blood pressure

Do not take fluoxetine if you:

- Are allergic to fluoxetine hydrochloride or any of the ingredients in fluoxetine hydrochloride capsules. See the end of this Medication Guide for a complete list of ingredients in fluoxetine hydrochloride capsules.
- 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.
- Take fluoxetine within 2 weeks of stopping an MAOI, unless directed to do so by your physician.
- Take fluoxetine if you stopped taking an MAOI within 5 weeks of stopping fluoxetine, unless directed to do so by your physician.
- Do not take fluoxetine if you are taking a Monoamine Oxidase Inhibitor (MAOI)

**Who should not take fluoxetine?**

- Any of these symptoms:
  - Swelling of the face, tongue, eyes or mouth
  - Rash, 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 appetite or weight.** 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.** This condition can be life-threatening. Symptoms may include:
   - Fast, slow, or irregular heartbeat
   - Shortness of breath
   - Dizziness or fainting

**Do not stop fluoxetine without first talking to your healthcare provider.**

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*
- Depressive episodes associated with Bipolar I Disorder, taken with olanzapine (Zyprexa)*

*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?**

- 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.

**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.

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**Who should not take fluoxetine?**

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- 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)
Common possible side effects in people who take fluoxetine include:

- 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, talk to your pharmacist or healthcare provider.

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 at 25°C (77°F); excursions permitted to 15º to 30ºC (59 to 86°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 Northstar Rx LLC at 1-800-206-7821.

What are the ingredients in fluoxetine?

Active ingredient: Fluoxetine hydrochloride

Inactive ingredients in capsules: lactose monohydrate, microcrystalline cellulose, colloidal silicon dioxide, gelatin, titanium dioxide, FD&C Blue No. 1 and FD&C Red No. 40.

This Medication Guide has been approved by the U.S. Food and Drug Administration.


Manufactured for: Northstar Rx LLC
Memphis, TN 38141
Toll free: 1-800-206-7821

Manufactured by: Alemic Pharmaceuticals Limited
(Formulation Division),
Village Panelav, P. O. Tajpura, Near Baska,
Taluka-Halol, Panchmahal, Gujarat, India.

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Revised: 04/2017