**ABNORMALITIES AND AESEPSIS**

1. Obsessive Compulsive Disorder

- Data from long term trials suggest that, while there is no body of evidence to answer the question of how long a patient treated with fluoxetine and olanzapine should be continued, the majority of patients who respond to treatment maintain their response for at least a year after stopping treatment.

- The recommend long-term treatment for patients with OCD is 5-10 years of treatment. If a patient with OCD is to discontinue treatment, gradually taper over at least 4 weeks.

- Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that the drug does not adversely affect their ability to engage in such activities.

- The use of fluoxetine in pregnant women. Results of a number of published epidemiological studies assessing the risk of congenital anomalies have been conflicting. Several recent case reports of conduction abnormalities that resulted in heart block have been reported. Because we do not know how long the risk of this adverse effect lasts, the use of fluoxetine in pregnant women is not recommended.

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Fluoxetine hydrochloride is a selective serotonin reuptake inhibitor (SSRI) available in 10 mg and 20 mg tablets. It is used to treat depression, bulimia, and obsessive-compulsive disorder (OCD).

**Dosage and Administration**

- **Depression**: The recommended dosage is 20 mg once daily. The dose can be increased to 40 mg once daily if needed, but not more than 60 mg/day.
- **Bulimia**: The recommended dosage is 20 mg once daily. The dose can be increased to 40 mg once daily if needed, but not more than 60 mg/day.
- **OCD**: The recommended dosage is 20 mg once daily. The dose can be increased to 40 mg once daily if needed, but not more than 60 mg/day.

**Side Effects**

Common side effects include:
- Nausea
- Diarrhea
- Insomnia
- Headache
- Dry mouth

Less common side effects include:
- Sexual problems
- Anxiety
- Irritability
- Mania

Rare side effects include:
- Seizures
- Tilt phenomenon
- Difficulty moving

**Interactions**

Fluoxetine can interact with many other medications, including SSRIs, antagonists, and MAOIs. Avoid using these medications together without consulting your healthcare provider.

**Warnings and Precautions**

- Fluoxetine can cause sedation, so patients should avoid driving or operating heavy machinery for the first few days of treatment.
- Fluoxetine can cause bleeding and should be used with caution in patients with bleeding disorders.
- Fluoxetine can cause cardiac arrhythmias and should be used with caution in patients with heart disease.

**Contraindications**

Fluoxetine is contraindicated in patients with a history of suicidal thoughts or behavior and in patients with a known hypersensitivity to fluoxetine.

**Geriatric Use**

Fluoxetine is generally well tolerated in elderly patients, but it may cause more sedation and dizziness in this population.

**Children Use**

Fluoxetine is not recommended for children under the age of 18 due to the risk of suicide. It is approved for use in children over 12 years of age.}

**References**

MEDICATION GUIDE
FLUOXETINE TABLETS, USP
(floo ox’ e teen)
10 mg and 20 mg

Read the Medication Guide that comes with fluoxetine tablets 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 tablets?
Fluoxetine tablets and other antidepressant medicines may cause serious side effects, including:
1. Suicidal thoughts or actions:
   - Fluoxetine tablets 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:
     o New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
     o Pay particular attention to such changes when fluoxetine tablets are 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 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 tablets 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, or mouth
   - rash, itchy welts (hives) or blisters, alone or with fever or joint pain

4. Visual problems:
   - eye pain
   - changes in vision
   - swelling or redness in or around the eye
   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.

5. Abnormal bleeding: Fluoxetine tablets 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.

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 (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

Do not stop fluoxetine tablets without first talking to your healthcare provider. Stopping fluoxetine tablets 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 are fluoxetine tablets?
Fluoxetine tablets are 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 tablets are 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 tablets treatment.

Who should not take fluoxetine tablets?
Do not take fluoxetine tablets if you:
- are allergic to fluoxetine hydrochloride or any of the ingredients in fluoxetine tablets. See the end of this Medication Guide for a complete list of ingredients in fluoxetine tablets.
- 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.
  o Do not take an MAOI within 5 weeks of stopping fluoxetine tablets unless directed to do so by your physician.
  o Do not start fluoxetine tablets if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take fluoxetine tablets 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 Melanil® (thioridazine). Do not take Melanil® within 5 weeks of stopping fluoxetine tablets because this can cause serious heart rhythm problems or sudden death.
• take the antipsychotic medicine pimozide (Brasp®) because this can cause serious heart problems.

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

Before starting fluoxetine tablets, 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 triptycic, lithium, bupropine, SSRIS, SNRIS, MAOIs or antipsychotics
  • Tramadol and fentanyl
  • 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. Some fluoxetine may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking fluoxetine tablets.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Fluoxetine tablets 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 tablets with your other medicines. Do not start or stop any medicine while taking fluoxetine tablets without talking to your healthcare provider first.

If you take fluoxetine tablets, you should not take any other medicines that contain fluoxetine hydrochloride including:
• Symbax®
• Sarafem®
• Prozac Weekly®

How should I take fluoxetine tablets?
• Take fluoxetine tablets exactly as prescribed. Your healthcare provider may need to change the dose of fluoxetine tablets until it is the right dose for you.
• Fluoxetine tablets may be taken with or without food.
• If you miss a dose of fluoxetine tablets, 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 tablets at the same time.
• If you take too much fluoxetine tablets, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking fluoxetine tablets?
Fluoxetine tablets 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 tablets affect you. Do not drink alcohol while using fluoxetine tablets.

What are the possible side effects of fluoxetine tablets?
Fluoxetine tablets may cause serious side effects, including:
• See “What is the most important information I should know about fluoxetine tablets?”
• Problems with blood sugar control. People who have diabetes and take fluoxetine tablets may have problems with low blood sugar while taking fluoxetine tablets. High blood sugar can happen when fluoxetine tablets are stopped. Your healthcare provider may need to change the dose of your diabetes medicines when you start or stop taking fluoxetine tablets.
• Feeling anxious or trouble sleeping
Common possible side effects in people who take fluoxetine tablets 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
• uriating 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 tablets.

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 tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store fluoxetine tablets?
• Store fluoxetine tablets at 20° to 25°C (68° to 77°F).
• Keep fluoxetine tablets away from light.
• Keep fluoxetine tablets bottle closed tightly

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

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

This Medication Guide summarizes the most important information about fluoxetine tablets. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about fluoxetine tablets that is written for healthcare professionals.
For more information about fluoxetine tablets, call Mylan Pharmaceuticals Inc. at 1-877-446-3769 (1-877-4-INFO-RR).

What are the ingredients in fluoxetine tablets, USP?
Active ingredients: fluoxetine hydrochloride, USP
Inactive ingredients: crosovidone, hypromellose, magnesium stearate, maize (corn) starch, microcrystalline cellulose, polyethylene glycol, silica colloidal anhydrous, and titanium dioxide.
This Medication Guide has been approved by the U.S. Food and Drug Administration.

The brands listed are trademarks of their respective owners.

[Table of ingredients]
MEDICATION GUIDE FLUOXETINE TABLETS, USP
(fool ox’een tablets)
10 mg and 20 mg

Fluoxetine tablets are a prescription medicine used to treat:
• Depressive Disorder*• Obsessive Compulsive Disorder (OCD)• Panic Disorder

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

Fluoxetine tablets are used to treat:
• Major Depressive Disorder*• Obsessive Compulsive Disorder (OCD)• Panic Disorder

Do not start fluoxetine tablets without first talking to your healthcare provider. Stopping fluoxetine tablets too quickly may cause serious symptoms including:
• anxiety,• high or low blood pressure,• feeling of changes in speed of body parts

Be sure to talk to your healthcare provider before you stop taking fluoxetine tablets. You may not feel better right away. Stopping fluoxetine tablets before you are done:
• may cause serious or life-threatening side effects. Get medical help right away if you have any of the following symptoms, or call 911 if an emergency, especially if you are new, worse, or worse than normal for you:
• confusion or agitation• Racing heart• Hallucinations or delusions• New or worsening trouble breathing• Nausea or vomiting• Seizures or convulsions 7. Other allergic reactions:
• Trouble breathing• Swelling of the face, tongue, or eyes • Swelling that is hard or itchy, alone or with fever or joint pain 8. Visual changes:
• Eye pain• Changes in vision• Swelling or redness in or around the eye Only some people are at risk for these problems. You may not want to use fluoxetine tablets if you are at risk for these problems and require treatment for them.

What should I watch for while taking fluoxetine tablets? Fluoxetine tablets may be associated with these serious side effects:
• Confusion or agitation• Racing heart• Hallucinations or delusions• New or worsening trouble breathing• Nausea or vomiting• Seizures or convulsions 7. Other allergic reactions:
• Trouble breathing• Swelling of the face, tongue, or eyes • Swelling that is hard or itchy, alone or with fever or joint pain 8. Visual changes:
• Eye pain• Changes in vision• Swelling or redness in or around the eye

People who take fluoxetine tablets close in time to an MAOI have more serious or even fatal side effects. The medical help right away if you have any of these symptoms:
• High fever• Uncontrolled muscle spasms• Rapid changes in heart rate or blood pressure• Confusion• Hallucinations or delusions (pass out)

Mellotol® (thioridazine). Do not take Mellaril® (thioridazine). Do not take Mellaril® (thioridazine) if you have had an allergic reaction to this medicine because this can cause serious heart problems.

Do not start fluoxetine tablets if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.

People who take fluoxetine tablets close in time to an MAOI may have serious or even fatal side effects. The medical help right away if you have any of these symptoms:
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• High fever• Uncontrolled muscle spasms• Rapid changes in heart rate or blood pressure• Confusion

Do not start fluoxetine tablets if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.
Medicines may interact with each other, may not work as well, or may work too well.

Before starting fluoxetine tablets? Ask if you are not sure.

Fluoxetine tablets include:

- Polyethylene glycol, silica colloidal anhydrous, and titanium dioxide.
- Other side effects in children and adolescents include:
  - Increased thirst
  - Abnormal increase in muscle movement or agitation
  - Agitation
  - Increased sweating
  - Tremor
  - Shaking
  - Weakness, or dry mouth
  - Loss of appetite, diarrhea, indigestion, nausea or vomiting,
  - Indigestion,
  - Indigestion, diarrhea, indigestion, nausea or vomiting,
  - Dryness of mouth
  - Loss of appetite, diarrhea, indigestion, nausea or vomiting,
  - Diarrhea,
  - Nausea, or vomiting
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  - Loss of appetite, diarrhea, indigestion, nausea or vomiting,
  - Diarrhea,
  - Nausea, or vomiting
  - Loss of appetite, diarrhea, indigestion, nausea or vomiting,
  - Diarrhea,
  - Nausea, or vomiting
  - Loss of appetite, diarrhea, indigestion, nausea or vomiting,
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