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Fluvoxamine: Patient drug information

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(For additional information see "Fluvoxamine: Drug information" and see "Fluvoxamine: Pediatric drug information")

Brand Names: US Luvox CR [DSC]

Brand Names: Canada Luvox

Warning

- Drugs like this one have raised the chance of suicidal thoughts or actions in children and young adults. The risk may be greater in people who have had these thoughts or actions in the past. All people who take this drug need to be watched closely. Call the doctor right away if signs like low mood (depression), nervousness, restlessness, grouchiness, panic attacks, or changes in mood or actions are new or worse. Call the doctor right away if any thoughts or actions of suicide occur.
- This drug is not approved for use in all children. Talk with the doctor to be sure that this drug is right for your child.

What is this drug used for?

- It is used to treat obsessive-compulsive problems.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to fluvoxamine or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have seizures.
- If you are taking any of these drugs: Linezolid or methylene blue.

- If you are taking any of these drugs: Alosetron, pimozide, ramelteon, thioridazine, or tizanidine.
- If you have taken certain drugs used for low mood (depression) like isocarboxazid, phenelzine, or tranylcypromine or drugs used for Parkinson's disease like selegiline or rasagiline in the last 14 days. Taking this drug within 14 days of those drugs can cause very bad high blood pressure.
- If you are breast-feeding or plan to breast-feed.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of side effects. If you need to stop this drug, you will want to slowly stop it as ordered by your doctor.
- If you smoke, talk with your doctor.
- Avoid drinking alcohol while taking this drug.
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- This drug may raise the chance of bleeding. Sometimes, bleeding can be life-threatening. Talk with the doctor.
- Some people may have a higher chance of eye problems with this drug. Your doctor may want you to have an eye exam to see if you have a higher chance of these eye problems. Call your doctor right away if you have eye pain, change in eyesight, or swelling or redness in or around the eye.
- It may take several weeks to see the full effects.
- This drug can cause low sodium levels. Very low sodium levels can be life-threatening, leading to seizures, passing out, trouble breathing, or death. Talk with the doctor.
- This drug may affect how much of some other drugs are in your body. If you are taking other drugs, talk with your doctor. You may need to have your blood work checked more closely while taking this drug with your other drugs.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.
- Use with care in children. Talk with the doctor.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Taking this drug in the third trimester of pregnancy may lead to some health problems in the newborn. Talk with the doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of low sodium levels like headache, trouble focusing, memory problems, feeling confused, weakness, seizures, or change in balance.
- Signs of bleeding like throwing up blood or throw up that looks like coffee grounds; coughing up blood; blood in the urine; black, red, or tarry stools; bleeding from the gums; vaginal bleeding that is not normal; bruises without a reason or that get bigger; or any bleeding that is very bad or that you cannot stop.
- A big weight gain or loss.
- Passing urine more often.
- · Sex problems like lowered interest in sex or ejaculation problems.
- · Seizures.
- Period (menstrual) changes.
- A very bad and sometimes deadly health problem called serotonin syndrome may happen. The risk may
 be greater if you take this drug with drugs for depression, migraines, or certain other drugs. Call your
 doctor right away if you have agitation; change in balance; confusion; hallucinations; fever; fast or
 abnormal heartbeat; flushing; muscle twitching or stiffness; seizures; shivering or shaking; sweating a lot;
 very bad diarrhea, upset stomach, or throwing up; or very bad headache.
- Call your doctor right away if you have a painful erection (hard penis) or an erection that lasts for longer than 4 hours. This may happen even when you are not having sex. If this is not treated right away, it may lead to lasting sex problems and you may not be able to have sex.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dizziness.
- · Upset stomach or throwing up.
- Dry mouth.
- Feeling sleepy.
- · Not able to sleep.
- · Headache.
- · Feeling tired or weak.
- Not hungry.
- · Loose stools (diarrhea).
- Constipation.
- Gas.
- Change in taste.

- Feeling nervous and excitable.
- · Sweating a lot.
- Shakiness.
- Signs of a common cold.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely. **All products:**

- Take with or without food.
- Take at bedtime if you are taking once a day.
- To gain the most benefit, do not miss doses.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

Long-acting capsules:

• Swallow whole. Do not chew, open, or crush.

What do I do if I miss a dose?

- · Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- Store in a dry place. Do not store in a bathroom.
- Protect from light.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.

- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Topic 12495 Version 138.0