

## **Luvox (fluvoxamine)**

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### **FDA ALERT [07/2005] Suicidal Thoughts or Actions in Children and Adults**

Patients with depression or other mental illnesses often think about or attempt suicide. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior (or their care givers) should contact their healthcare professional right away.

#### *Children*

Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Although Lexapro is prescribed for children, FDA has not approved Lexapro for use in children.

#### *Adults*

Several recent scientific publications report the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications. Even before these reports became available, FDA began a complete review of all available data to determine whether there is an increased risk of suicidal thinking or behavior in adults being treated with antidepressant medications. It is expected that this review will take a year or longer to complete. In the meantime, FDA is highlighting that adults being treated with antidepressant medication, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior.

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information.*

### **FDA ALERT [07/2006] – Potentially Life- Threatening Serotonin Syndrome When Used With Triptan Medicines**

A life-threatening condition called serotonin syndrome can happen when medicines called selective serotonin reuptake inhibitors (SSRIs), such as Luvox®, and medicines used to treat migraine headaches known “triptans” (e.g. sumatriptan/ Imitrex®) are used together. Signs and symptoms of serotonin syndrome may include: restlessness, hallucinations, loss of coordination, fast heart beat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhea, nausea, vomiting and coma.

Serotonin syndrome may be more likely to occur when starting or increasing the dose of an SSRI or a triptan. Before you take Luvox® and a triptan together, talk to your healthcare professional. If you must take these medicines together, be aware of the possibility of serotonin syndrome, and get medical care right away if you think serotonin syndrome is happening to you.

*This information reflects the FDA’s current analysis of data available to FDA concerning this drug*

### **FDA ALERT [07/2006] – Infant Persistent Pulmonary Hypertension**

The results of a study that looked at the use of antidepressant medicines during pregnancy in mothers of babies born with a serious condition called persistent pulmonary hypertension of the newborn (PPHN) was recently published in a medical journal. Babies born with PPHN have abnormal blood flow through the heart and lungs and do not get enough oxygen to their bodies. Babies with PPHN can be very sick and may die.

The study results showed that babies born to mothers who took selective serotonin reuptake inhibitors (SSRIs), the family of medicines Luvox® belongs to, 20 weeks or later in their pregnancies had a higher chance (were 6 times as likely) to have PPHN than babies born to mothers who did not take antidepressants during pregnancy (6-12 per 1000 births versus 1-2 per 1000 births).

The FDA plans to further look at the role of SSRIs in babies with PPHN. Talk to your doctor if you are taking Luvox® and are pregnant or are planning to have a baby. You and your doctor will need to talk about the best way to treat your depression during pregnancy.

*This information reflects the FDA’s current analysis of data available to FDA concerning this drug*

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#### **Brand and Generic Names:**

- Brand name = Luvox®

No longer manufactured

- Generic name = Fluvoxamine

Tablets: 25 mg, 50 mg, 100 mg

### **What is Luvox® and what does it treat?**

Fluvoxamine is a selective serotonin reuptake inhibitor (SSRI) antidepressant which is FDA approved for the treatment of obsessive compulsive disorder (OCD).

OCD occurs when a person experiences the following symptoms at the same time: obsessions (unwanted, recurrent and disturbing thoughts) and compulsions (repetitive, ritualized behaviors that the person feels driven to perform in order to lessen the anxiety produced by the obsessions).

### **What is the most important information I should know about Luvox®?**

After starting fluvoxamine, symptoms gradually decrease over a period of weeks. Most patients with OCD who have responded to fluvoxamine will need to stay on the medication for prolonged periods of time, often years, to avoid relapse. Studies have indicated that this is both safe and effective, but it is important to remain under the supervision of your physician for as long as you continue taking any medication.

Do not stop taking fluvoxamine or change your dose without talking to with your healthcare provider first.

Stopping fluvoxamine abruptly may result in one or more of the following withdrawal symptoms: irritability, nausea, dizziness, vomiting, nightmares, headache and paresthesias (prickling, tingling sensation on the skin).

Because depression is also a part of Bipolar illness, people who take antidepressants may be at risk for "switching" from depression into mania. Symptoms of mania include "high" or irritable mood, very high self esteem, decreased need for sleep, pressure to keep talking, racing thoughts, being easily distracted, frequently involved in activities with a large risk for bad consequences (for example, excessive buying sprees).

### **Are there specific concerns about Luvox® and pregnancy?**

If you are planning on becoming pregnant, notify your healthcare provider so that he/she can best manage your medications. People living with OCD who wish to become pregnant face important decisions, each with risks and benefits. There are many dimensions to these choices, so be sure to confer with your doctor and caregivers.

For mothers who have taken SSRIs during their pregnancy, there appears to be less than a 1% chance of infants developing persistent pulmonary hypertension. This is a potentially fatal condition that is associated with use of antidepressants that are similar to

fluvoxamine in the second half of pregnancy. If you are pregnant, please discuss the risks and benefits of this medication use with your healthcare provider.

Regarding breast-feeding, caution is advised since fluvoxamine does pass into breast milk

### **What should I discuss with my healthcare provider before taking Luvox®?**

- The most bothersome symptoms of your condition
- If you have thoughts of suicide
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- Any medical problems that you may have
- All other medications you are currently taking and any medication allergies you have
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you drink alcohol or use drugs

### **How should I take Luvox®?**

Fluvoxamine is usually taken two times per day with or without food.

While the total daily dose usually ranges from 50 mg to 200 mg, your healthcare provider will determine the dose that is right for you based upon your response.

### **What happens if I miss a dose of Luvox®?**

If you miss a dose of fluvoxamine, take it as soon as you remember unless it is close to when your next dose is due. If you missed a dose of medication and it is close to the time of your next dose, skip the missed dose and take your next dose at the regularly scheduled time. Do not double your next dose or take more than your prescribed dose.

### **What should I avoid while taking Luvox®?**

Avoid drinking alcohol or using illegal drugs while you are taking antidepressant medications because the beneficial effects of the medication may be decreased and adverse effects may be increased (e.g. sedation).

### **What happens if I overdose with Luvox®?**

If an overdose occurs, whether intentional or accidental, immediate medical attention may be necessary. Call your doctor or emergency medical service (911). You may also contact the poison control center (1-800-222-1222).

Symptoms of overdose include drowsiness, nausea, vomiting, abdominal pain, tremor, slow heart rate, and seizures. A specific antidote does not exist.

### **What are the possible side effects of Luvox®?**

Side effects with fluvoxamine are generally mild and are similar to those reported with other SSRI antidepressants. The most commonly reported side effects are increased sweating, sleepiness, insomnia, nausea, diarrhea, tremor, dry mouth, loss of strength, headache, weight loss or gain, dizziness, and restlessness. If you experience side effects after starting fluvoxamine they will often improve over the first week or two as you continue to take the medication. Sexual side effects such as problems with ejaculation may also occur, and often do not diminish over time.

### **Are there any risks for taking Luvox® for long periods of time?**

To date, there are no known problems associated with long term use of fluvoxamine. It is a safe and effective medication when used as directed.

### **What other drugs may interact with Luvox®?**

Fluvoxamine should not be taken with or within two weeks of taking monoamine oxidase inhibitors (MAOIs). These include phenelzine (Nardil®), tranylcypromine (Parnate®), isocarboxazid (Marplan®) and selegiline (Emsam®).

Although rare, there is an increased risk of serotonin syndrome when fluvoxamine is used with other medications that increase serotonin such as other antidepressants, migraine medications called “triptans” (e.g. Imitrex®) and the analgesic tramadol (Ultram®).

Always let your doctor know what other prescription, over-the-counter, and herbal medications you are taking.

### **How long does it take for Luvox® to work?**

Like most other medications used for OCD, fluvoxamine may take several weeks before it is fully effective. It is important to give the medication sufficient time before judging whether it will work for a given person.

*Updated by  
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(March 2007)*



NAMI wishes to thank the [College of Psychiatric and Neurological Pharmacists](#) for producing this fact sheet.

*Reviewed by Dr. Ken Duckworth, NAMI Medical Director*

**For more information please contact the pharmaceutical company listed below.**

Solvay Pharmaceuticals, Inc.	901 Sawyer Rd. Marietta, GA 30062	770-578- 9000	<u><a href="http://www.solvaypharmaceuticals-us.com">www.solvaypharmaceuticals- us.com</a></u>
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**Patient Prescription Drug Assistance Programs - Free or low-cost medications provided by pharmaceutical companies**

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

**RX Assistance Program 1-800-256-8918**