



# Luvox and Luvox CR (fluvoxamine)

Generic name: Fluvoxamine

Available strengths: 25 mg, 50 mg, 100 mg tablets;

100 mg, 150 mg sustained-release capsules (Luvox CR)

Available in generic: Yes

Drug class: Selective serotonin reuptake inhibitor antidepressant

## General Information

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**Luvox (fluvoxamine)** was approved by the U.S. Food and Drug Administration (FDA) for the treatment of obsessive-compulsive disorder (OCD) and social anxiety disorder, but not depression. The use of a medication for its approved indications is called its *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* (“off-label”) uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of those treatments. Physicians may use Luvox for treatment of major depression, panic disorder, posttraumatic stress disorder, premenstrual dysphoric disorder, nocturnal enuresis (incontinence of urine) in children, and bulimia nervosa.

Luvox is a **serotonin**-specific medication that works by blocking the reuptake of the neurotransmitter serotonin back into brain cells, thereby increasing its levels in the brain. OCD, depression, and other mental disorders may be caused by abnormally low levels of serotonin. This abnormality may in turn produce changes in affected areas of the brain, resulting in psychiatric symptoms such as depression or anxiety. The presumed action of Luvox and other selective serotonin reuptake inhibitors (SSRIs) is to increase serotonin levels, which may help to restore those areas of the brain to normal functioning. OCD may also be successfully treated with other SSRIs as well as the tricyclic antidepressant (TCA) Anafranil (clomipramine).

## Dosing Information

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The recommended starting dose of Luvox is 50 mg as a single bedtime dose. The dose is increased weekly in increments of 25–50 mg. The maximum dosage should not exceed 300 mg/day. When dosages are greater than 100 mg/day, Luvox should be taken twice a day, in either equally divided doses or with the larger dose at

bedtime. The inconvenience of twice-daily dosing may be circumvented by switching to Luvox CR, which can be administered as a single dose at bedtime. Seniors and people with severe and chronic illness may require lower dosages (50–100 mg/day) than the average person.

In treating children (ages 8–17 years) with OCD, the recommended starting dose is 25 mg administered as a single bedtime dose. The dose is increased by 25 mg every 4–7 days until clinical response is achieved. Generally, the dosage for children up to 11 years old should not exceed 200 mg/day, whereas adolescents may require a maximum dosage of 300 mg/day, similar to the average adult. Girls, in general, may require lower dosages.

## Common Side Effects

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The most frequently reported side effects with Luvox are gastrointestinal disturbance, principally nausea, vomiting, indigestion, diarrhea, or loose stools. Nervousness, jitteriness, and trouble sleeping are other commonly reported side effects. Occasionally, individuals may experience headaches, sleepiness, and excessive sweating.

Luvox may induce sexual dysfunction in both men and women. The sexual side effects reported are delayed orgasm in women and retarded ejaculation in men. Some people may experience decreased desire or lack of interest in sexual activity. However, the adverse effects on sexual function with Luvox are generally less frequent than with Prozac or Paxil.

Patients should discuss these side effects with their physician, especially if they continue to be bothersome 3–4 weeks after the medication is started. If a rash or any other severe symptoms develop, patients should contact their physician immediately.

## Adverse Reactions and Precautions

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Luvox may cause drowsiness in some people. Patients should not drive or operate machinery until they are certain that their alertness or coordination is not affected by the medication. Patients with a known allergy to Luvox or who have experienced a severe reaction after taking it should not take Luvox.

## Use in Pregnancy and Breastfeeding: Pregnancy Category C

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Luvox has not been tested in women to determine its safety in pregnancy. The effects of the medication on the developing fetus in pregnant women are unknown. However, newborn babies exposed to antidepressants such as SSRIs late in the third trimester developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Women who are pregnant or may become pregnant should discuss this with their physician. Some women may experience a recurrence of their depression when they stop their antidepressant. In these circumstances it may be necessary to restart the medication or seek an alternative medication or treatment.

Nursing mothers should not take Luvox because small amounts will pass into breast milk and be ingested by the baby. If stopping the drug is not an alternative, breastfeeding should not be started or should be discontinued.

## Possible Drug Interactions

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The combined use of Luvox with certain other medications may result in adverse drug interactions, because one medication may alter the blood levels of the other. The clinically significant drug interactions reported with Luvox are summarized in the table on the next page.

Coumadin (warfarin)	Luvox may increase Coumadin levels and its anticoagulant effects, resulting in bleeding; Coumadin therapy should be monitored closely when starting any SSRI.
Tricyclic antidepressants (TCAs)	Luvox may increase the levels of TCAs and the potential for toxicity.
Clozaril (clozapine)	Luvox may increase the levels of Clozaril and increase its potential for adverse side effects.
Theophylline	Luvox may elevate levels of theophylline and cause toxicity; consequently, theophylline levels should be monitored closely.
Tegretol (carbamazepine)	Luvox may increase levels of Tegretol, possibly resulting in toxicity.
Smoking	Smoking may lower blood levels and decrease the effectiveness of Luvox. Smokers may require higher doses than nonsmokers.

Other medications, including herbal supplements (such as St. John's wort), that boost serotonin may result in excessive levels of that neurotransmitter when combined with Luvox and produce a toxic syndrome known as **serotonin syndrome**. The early signs of serotonin syndrome are restlessness, confusion, tremors, flushing, and involuntary muscle jerks. If the medications are not stopped, the individual may develop more life-threatening complications resulting in muscle disorders, high fever, respiratory problems, clotting problems, and destruction of red blood cells that may lead to acute renal failure. Hence, patients taking Luvox should be alert to the possible signs of serotonin syndrome, which require immediate medical attention and discontinuation of the serotonin-boosting medications.

Antidepressants known as **monoamine oxidase inhibitors** (MAOIs) should not be taken together with Luvox, because the combination may potentially produce a toxic reaction that includes elevated temperature, high blood pressure, and extreme excitation and agitation. Patients should consult their physician or pharmacist before taking any new medications, including over-the-counter medications and herbal supplements, with Luvox.

Patients taking Luvox should avoid alcohol or should consume it in moderation because the combination may worsen depression.

## Overdose

Like other SSRIs, Luvox is much safer in overdose than the older TCAs and some of the newer antidepressants. However, fatal outcomes have been reported when Luvox was taken in combination with other medications.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency room for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

## Special Considerations

Most cases of major depression can be treated successfully, usually with medication, psychotherapy, or both. The combination of psychotherapy and antidepressants is very effective in treating moderate to severe depression. The medications improve mood, sleep, energy, and appetite while therapy strengthens coping skills, deals with possible underlying issues, and improves thought patterns and behavior.

In general, antidepressants alone help about 60%–70% of those taking them. Although a few individuals may experience some improvement from antidepressants by the end of the first week, most people do not see significant benefits from their antidepressants until after 3–4 weeks, and it can sometimes take as long as 8 weeks for the medication to produce its full effects. Thus it is critical that patients continue to take their antidepressant long enough for the medication to be beneficial and that patients not get discouraged and stop their medication prematurely if they do not feel better immediately.

In short-term studies, antidepressants were found to increase the risk of suicidal thinking and behavior in children and adolescents with major depression and other psychiatric disorders. The FDA requires the prescriber to warn of this risk in children and adolescents when starting antidepressant therapy. According to the FDA findings, the risk of suicidal thoughts and behaviors associated with antidepressants is age-related. This phenomenon tends to occur in the younger population and is most likely to occur early in the course of treatment. In adults over 24 years of age, there did not appear to be an increased risk of suicidality with antidepressants compared with placebo. In patients over age 65, the findings showed that antidepressants had a “protective effect” against suicidal thoughts and behavior. Other studies have found that when more people in a community are taking antidepressants, the suicide rate is lower.

The risk of suicide is inherent in depression and may persist until the individual responds to treatment. After starting or changing antidepressant therapy, the person, especially a child or adolescent, should be closely observed for worsening signs of depression, and the family or caregiver should communicate any concerns to the physician.

- **Warning:** Always let your physician or a family member know if you have suicidal thoughts. Notify your psychiatrist or your family physician whenever your depressive symptoms worsen or whenever you feel unable to control suicidal urges or thoughts.
- Do not discontinue Luvox abruptly. Your dosage should be tapered gradually to prevent discontinuation symptoms.
- If you miss a dose, take it as soon as possible, within 1–2 hours of the scheduled dose. If it is close to the next scheduled dose, skip the missed dose and continue on your regular dosing schedule. Do not take double doses.
- Luvox may be taken with or without food.
- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of your medication, and the medication may lose its therapeutic effects.
- Keep your medication out of reach of children.

***If you have any questions about your medication, consult your physician or pharmacist.***

## Notes

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