

PART III: CONSUMER INFORMATION

^{PR}LUVOX® fluvoxamine maleate

This leaflet is PART III of a three-part "Product Monograph" published when LUVOX® was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about LUVOX®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

LUVOX has been prescribed by your doctor to relieve your symptoms of:

- depression (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain), or
- obsessive-compulsive disorder (recurrent and intrusive thoughts, feelings, ideas or sensations; recurrent pattern of behaviour, or unwanted thoughts or actions)

What it does:

LUVOX belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants. Depression is thought to be caused, in part, by low levels of a chemical that occurs naturally in the brain, called serotonin. LUVOX is thought to work by increasing the levels of serotonin in the brain.

When it should not be used:

Do not use LUVOX if you are:

- allergic to it or any of the components of its formulation (See **What the non-medicinal ingredients are:**).
- currently taking or have recently taken monoamine oxidase (MAO) inhibitor antidepressants (e.g. phenelzine sulphate, moclobemide) or a MAO inhibitor antibiotic (e.g. linezolid).
- going to have, or recently had, a medical procedure that involved the use of methylene blue (an intravenous dye).
- currently taking or have recently taken thioridazine, mesoridazine, pimozone, terfenadine, astemizole, or cisapride.
- currently taking or have recently taken tizanidine.
- taking ramelteon, a sleep medicine not available in Canada.

What the medicinal ingredient is:

Fluvoxamine maleate.

What the non-medicinal ingredients are:

Colloidal anhydrous silica, maize starch, mannitol, hypromellose, polyethylene glycol 6000, pregelatinized starch, sodium stearyl fumarate, talc and titanium dioxide.

There is no gluten, lactose, sulfite or tartrazine in LUVOX.

What dosage forms it comes in:

LUVOX is available as:

- 50 mg white to off-white tablets stamped "291".
- 100 mg white to off-white tablets stamped "313".

WARNINGS AND PRECAUTIONS

LUVOX is not for use in children under 18 years of age.

During treatment with LUVOX or any type of antidepressant medication, it is important that you and your doctor have good ongoing communication about how you are feeling. Treatment with antidepressant medications is most safe and effective when you and your doctor have good communication about how you are feeling.

Changes in Feelings and Behaviour:

It is important that you have good communication with your doctor about how you feel. Discussing your feelings and treatment with a friend or relative who can tell you if they think you are getting worse is also useful.

Some patients may feel worse when first starting or changing the dose of drugs such as LUVOX. You may feel more anxious, agitated, hostile, or impulsive, or may have thoughts about suicide, self-harm or harm to others. These changes in feelings can happen in patients treated with drugs like LUVOX for any condition, and at any age, but it may be more likely in patients 18 to 24 years old. If this happens, see your doctor immediately. Do not stop taking LUVOX on your own.

Bone Fractures:

Taking LUVOX may increase your risk of breaking a bone if you are elderly or have osteoporosis or have other major risk factors for breaking a bone. You should take extra care to avoid falls especially if you get dizzy or have low blood pressure.

Medicines like LUVOX may affect your sperm. Fertility in some men may be reduced while taking LUVOX. This effect is reversible. Full impact on fertility in men is not yet known.

Angle-closure Glaucoma:

LUVOX can cause an acute attack of glaucoma. Having your eyes examined before you take LUVOX could help identify if you are at risk of having angle-closure glaucoma. Seek immediate medical attention if you experience:

- eye pain.
- changes in vision.
- swelling or redness in or around the eye.

Talk to your doctor or pharmacist before using LUVOX®:

- if you have had any allergic reaction to medications, food, etc.
- about all your medical conditions, including a history of seizures, liver or kidney disease, heart problems or a history of any abnormal bleeding.
- about any medications (prescription or over-the-counter) you are taking or have recently taken, especially monoamine oxidase (MAO) inhibitors (e.g., phenelzine sulphate, moclobemide), any other antidepressants, tizanidine, thioridazine, pimozone, mesoridazine, neuroleptics, clopidogrel, warfarin, propranolol, phenytoin, theophylline, lithium, tryptophan, terfenadine, astemizole, cisapride, triptans used to treat migraines, lithium, tramadol, drugs containing tryptophan, drugs used to prevent seizures (anticonvulsants).
- about any natural or herbal products you are taking (e.g., St. John's Wort).
- if you have a history or family history of mania/hypomania or bipolar disorder.
- if you have high or low blood sugar, or diabetes mellitus.
- if you have a bleeding disorder or a tendency to easily develop bruises, have been told that you have low platelets.
- if you have been told you have a low sodium level in the blood.
- if you had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- if you are pregnant, or are thinking about becoming pregnant, or if you are breast feeding.
- about your habits of alcohol and/or street drug consumption.
- if you drive a vehicle or perform hazardous tasks during your work.

Effects on Pregnancy and Newborns

LUVOX should not be used during pregnancy unless the benefit outweighs the risk.

If you are already taking LUVOX and have just found out that you are pregnant, you should talk to your doctor immediately. You should also talk to your doctor if you are planning to become pregnant. It is very important that you do NOT stop taking LUVOX without first talking to your doctor.

Some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer antidepressants, such as LUVOX, during pregnancy have developed complications at birth requiring prolonged hospitalization, breathing support and tube feeding. Reported symptoms included: feeding and / or breathing difficulties, vomiting, fits (or seizures), body temperature changes, stiff or floppy muscles, jitteriness, bluish skin, irritability, lethargy, drowsiness, difficulty in sleeping and constant crying.

In most cases, the newer antidepressant was taken during the third trimester of pregnancy. These symptoms are consistent with either a direct adverse effect of the antidepressant on the baby or possibly a discontinuation syndrome caused by sudden withdrawal from the drug. These symptoms normally resolve over time. However, if your baby experiences any of these symptoms, contact your doctor as soon as you can.

Persistent Pulmonary Hypertension (PPHN) and newer

antidepressants:

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like LUVOX may increase the risk of a serious lung condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), that causes breathing difficulties in newborns soon after birth, making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your doctor immediately.

If you are pregnant and taking an SSRI, or other newer antidepressants, you should discuss the risks and benefits of the various treatment options with your doctor. It is very important that you do NOT stop taking these medications without first consulting your doctor. See **SIDE EFFECTS AND WHAT TO DO ABOUT THEM** section for more information.

INTERACTIONS WITH THIS MEDICATION

Do not use LUVOX if you are taking or have recently taken monoamine oxidase (MAO) inhibitors, methylene blue (intravenous), linezolid, thioridazine, mesoridazine, pimozone, terfenadine, astemizole, cisapride, tizanidine or ramelteon (a sleep drug, not available in Canada).

Drugs that may interact with LUVOX® include:

- other antidepressants, such as SSRIs, SNRIs and certain tricyclics.
- other drugs that affect serotonin such as lithium, tramadol, tryptophan, St. John's Wort and triptans (used to treat migraines).
- certain medicines used to treat schizophrenia.
- certain medicines used to treat bipolar depression such as lithium.
- certain medicines used to treat epilepsy.
- certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g. clopidogrel, warfarin, dabigatran), acetylsalicylic acid (e.g. Aspirin) and other nonsteroidal anti-inflammatory drugs (e.g. ibuprofen).
- propranolol or other medications used to treat high blood pressure.
- certain medicines used to treat patients with irregular heart beats.
- certain drugs used to treat diabetes.
- certain medicines used to treat some respiratory conditions such as chronic obstructive pulmonary disease (COPD) or asthma (e.g., theophylline).
- certain medicines used to treat pain, such as fentanyl (used in anesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine.
- certain medicines used to treat cough such as dextromethorphan.
- sedatives such as benzodiazepines.

In general, drinking alcoholic beverages should be kept to a

minimum or avoided completely while taking LUVOX.

PROPER USE OF THIS MEDICATION

Usual dose:

- It is very important that you take LUVOX exactly as your doctor has instructed. Generally most people take between 100 mg to 200 mg per day for depression and between 100 mg and 300 mg for obsessive compulsive disorder.
- LUVOX is usually taken once a day at bedtime. However, doses above 150 mg per day may be divided so that a maximum of 150 mg is taken at bedtime. Swallow the tablets whole with water. Do not chew them.
- Establishing an effective dosage level will vary from one person to another. For this reason, your doctor may adjust your dosage gradually during treatment.
- As with all antidepressants, improvement with LUVOX is gradual. You should continue to take your medication even if you do not feel better, as it may take a number of weeks for your medicine to work. Continue to take LUVOX for as long as your doctor recommends.
- Never increase or decrease the amount of LUVOX you are taking unless your doctor tells you to change your dosage.
- Do not suddenly stop taking this medication without talking to your doctor first. Suddenly stopping treatment or changing the dose may cause unpleasant side effects (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).
- You should avoid taking St. John's Wort if you are taking LUVOX.

Reminder: This medicine has been prescribed only for you. Do not give it to anybody else as they may experience undesirable effects, which may be serious. If you have further questions, please ask your doctor or pharmacist.

Overdose:

In case of an overdose contact a health care practitioner, the regional Poison Control Centre, or the nearest hospital emergency department, even if you do not feel sick. Take your medicine with you.

Missed Dose:

If you miss a dose, do not try to make up for it by doubling up on the dose the next time. Just take your next regularly scheduled dose and try not to miss any more.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, LUVOX can cause some side effects. You may not experience any of them. For most patients, side effects are likely to be minor and temporary. However some may be

serious. Some of these side effects may be dose related. Consult your doctor if you experience these or other side effects, as the dose may have to be adjusted.

If you experience an allergic reaction (including red skin, hives, itching, swelling of the lips, face tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes) or any severe or unusual side effects, stop taking the drug and contact your doctor immediately.

The most common side effects of LUVOX are:

- nausea (sometimes with vomiting)
- constipation
- diarrhea
- loss of appetite
- upset stomach
- sleep disturbances
- dry mouth
- tremor (uncontrolled shaking)
- dizziness
- headache
- anxiety
- nervousness
- excessive sweating
- sexual problems
- urinating problems.

LUVOX does not usually affect people's normal activities. However, some people feel sleepy while taking it, in which case they should not drive or operate machinery.

Although psychiatric disorders may be associated with decreases in sexual desire, performance and satisfaction, treatment with this medication may also affect sexual functioning.

LUVOX can raise your levels of a hormone called "prolactin" (measured with a blood test). Symptoms of high prolactin may include: (in men) breast swelling, sexual dysfunction; (in women) breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle.

Discontinuation Symptoms

Contact your doctor before stopping or reducing your dosage of LUVOX. Symptoms such as dizziness, abnormal dreams, unusual skin sensations (burning, prickling, tingling), sleep disturbances (including insomnia and intense dreams) confusion, fatigue, agitation, irritability, anxiety, emotional instability, difficulty concentrating, headache, tremor, nausea, vomiting, diarrhea, sweating, palpitations (faster heartbeat) or other symptoms may occur suddenly after stopping or reducing the dosage of LUVOX. Such symptoms may also occur if a dose is missed. These symptoms usually disappear without needing treatment. Tell your doctor immediately if you have these or any other symptoms. Your doctor may adjust the dosage of LUVOX to alleviate the symptoms. Discontinuation symptoms may occur in an infant if the mother is taking antidepressants at, or shortly before, the time of birth or while nursing.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Seek immediate emergency medical assistance
		Only if severe	In all cases	
Common	Uncontrollable movements of the body or face		✓	
Uncommon	Allergic reactions: red and lumpy skin rash, hives, swelling, trouble breathing			✓
	Akathisia: feeling restless and unable to sit or stand still		✓	
	Hallucinations: strange visions or sounds		✓	
Unknown	Low platelets: Bruising or unusual bleeding from the skin or other areas		✓	
	Stevens Johnson Syndrome/Toxic Epidermal Necrolysis: Severe skin reactions, like skin rashes or redness, including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis)			✓
Rare	Low sodium level in the blood: tiredness, weakness, confusion, combined with achy, stiff or uncoordinated muscles		✓	
	Gastrointestinal bleeding: vomiting blood or passing blood in stools			✓
	Seizures: loss of consciousness with uncontrollable shaking			✓
	Liver disorder: nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Seek immediate emergency medical assistance
		Only if severe	In all cases	
	Serotonin syndrome/Neuroleptic Malignant Syndrome: a combination of most or all of the following: confusion, restlessness, sweating, shaking, shivering, nausea, diarrhea, vomiting, hallucinations, sudden jerking of the muscles, fast heartbeat, changes in blood pressure			✓
	Glaucoma: Eye pain, change in vision, swelling or redness in or around the eye			✓
See Warnings & Precautions	Changes in feelings or behaviour (anger, anxiety, agitation, hostility)		✓	
	Thoughts of death or suicide			✓
	Increased blood sugar: frequent urination, thirst and hunger		✓	
	Low blood sugar: symptoms of dizziness, lack of energy, drowsiness		✓	

This is not a complete list of side effects. For any unexpected effects while taking LUVOX®, contact your doctor or pharmacist.

HOW TO STORE IT

Store in a dry place at temperatures between 15 – 25°C. Protect from light. Keep LUVOX out of reach and sight of children. Keep container tightly closed. If your doctor tells you to stop taking LUVOX, please return any leftover medicine to your pharmacist.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full product monograph, prepared for health professionals can be found at:

www.hc-sc.gc.ca (Drug Product Database) or at www.mylan.ca or by contacting the sponsor, BGP Pharma ULC at: 1-844-596-9526

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