

## PART III: CONSUMER INFORMATION

### **LUVOX®** (fluvoxamine maleate)

This leaflet is part III of a three-part "Product Monograph" 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.

Please read this information before you start to take your medicine, even if you have taken this drug before. Keep this information with your medicine in case you need to read it again.

#### 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 thought, feeling, idea or sensation; recurrent pattern of behaviour, or unwanted thoughts or actions)

##### **What it does:**

LUVOX belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). LUVOX is thought to work by increasing the levels of a chemical in the brain called serotonin.

##### **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 nonmedicinal 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).
- Currently taking or have recently taken thioridazine or pimozide.

##### **What the medicinal ingredient is:**

Fluvoxamine maleate.

##### **What the nonmedicinal 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 and 100 mg white to off-white tablets.

#### WARNINGS AND PRECAUTIONS

**During treatment with these types of medications, it is important that you and your doctor have good ongoing communication about how you are feeling.**

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

##### **New or Worsened Emotional or Behaviour Problems**

Particularly in the first few weeks or when doses are adjusted, a small number of patients taking drugs of this type may feel worse instead of better; for example, they may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of self-harm or harm to others. Should this happen to you, or those in your care if you are a caregiver or guardian, consult your doctor immediately. Close observation by a doctor is necessary in this situation. **Do not discontinue your medication on your own.**

##### **BEFORE you use LUVOX tell your doctor or pharmacist:**

- if you have had any allergic reaction to medications
- all your medical conditions, including a history of seizures, liver or kidney disease, heart problems or a history of any abnormal bleeding
- any medications (prescription or non-prescription) you are taking or have recently taken, especially monoamine oxidase (MAO) inhibitors (e.g., phenelzine sulphate, moclobemide), or any other antidepressants, tizanidine, thioridazine, pimozide, mesoridazine, neuroleptics, warfarin, propranolol, phenytoin, theophylline, lithium, tryptophan, terfenadine, astemizole, cisapride, and drugs used to prevent seizures (anticonvulsants)
- if you have ever had any allergic reaction to medications, food, etc.
- any natural or herbal products you are taking (e.g., St. John's Wort)
- whether you are pregnant, or thinking about becoming pregnant, or if you are breast feeding
- 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**

Post-marketing reports indicate that some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer anti-depressants, 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, seizures, tense or overly relaxed muscles, jitteriness and constant crying.

In most cases, the newer anti-depressant was taken during the third trimester of pregnancy. These symptoms are consistent with either a direct adverse effect of the anti-depressant 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.

Preliminary information suggests that use of SSRIs during the second half of pregnancy may be associated with an increased rate of a serious lung condition (PPHN) that causes breathing difficulties in newborns soon after birth. According to the study, babies born with this condition were 6 times more likely than healthy babies to have been exposed to SSRIs. In the general population, PPHN is known to occur at a rate of about 1-2 per 1000 newborns.

If you are pregnant and taking an SSRI, or other newer anti-depressants, 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, thioridazine or pimozide.**

**LUVOX should not be used with tizanidine, terfenadine, astemizole and cisapride.**

You should tell your doctor if you are taking or have recently taken any medications (prescription, non-prescription or natural/herbal), especially:

- other antidepressants, such as SSRIs and certain tricyclics
- other drugs that affect serotonin such as lithium, linezolid, 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., warfarin), acetylsalicylic acid (e.g., Aspirin) and other non-steroidal 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)
- 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.
- Never increase or decrease the amount of LUVOX you are taking unless your doctor tells you to change your dosage.
- Do not stop taking this medication without consulting your doctor.
- 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.
- Talk to your doctor before you stop taking your medication on your own.
- 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.**

### 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.

### Overdose:

In case of an overdose contact your doctor, the regional Poison Control Centre, or the nearest hospital emergency department, even if you do not feel sick.

## 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.

**New or Worsened Emotional or Behavioural Problems**

Particularly in the first few weeks or when doses are adjusted, a small number of patients taking a drug of this type may feel worse instead of better; for example, they may experience new or worsened feelings of agitation, hostility, anxiety, or thoughts about suicide or harming others. Your doctor should be informed of such changes immediately. Close observation by a doctor is necessary in this situation. Do not discontinue your medication on your own. See also the WARNINGS AND PRECAUTIONS section.

Depression and other serious mental illness are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions. A recent U.S. Food and Drug Administration review showed that antidepressants may increase suicidal thoughts or actions in young adults (18 to 24 years of age). Suicidal thoughts and actions do not necessarily decrease above 24 years of age.

Inform your doctor, caregiver, guardian or a family member if you are having any suicidal thoughts. Your doctor should evaluate you for signs of your suicidal behaviour, including looking for emotional and behavioural changes. Your doctor may recommend increased supervision, irrespective of your age.

**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), confusion, fatigue, agitation, anxiety, difficulty concentrating, headache, tremor, nausea, vomiting, sweating or other symptoms may occur 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.

**Effects on Newborns**

Some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer antidepressants during pregnancy have shown such symptoms as breathing and feeding difficulties, jitteriness and constant crying. If your baby experiences any of these symptoms, contact your doctor as soon as you can. See WARNINGS AND PRECAUTIONS section for more information.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
<b>Symptom / effect</b>		<b>Talk with your doctor or pharmacist</b>		<b>Seek immediate emergency medical assistance</b>
		<b>Only if severe</b>	<b>In all cases</b>	
<b>Common</b>	Uncontrollable movements of the body or face		✓	
<b>Uncommon</b>	Allergic reactions [red and lumpy skin rash, hives, swelling, trouble breathing]			✓
<b>Uncommon</b>	Akathisia [feeling restless and unable to sit or stand still]		✓	
<b>Uncommon</b>	Hallucinations [strange visions or sounds]		✓	
<b>Rare</b>	Bruising or unusual bleeding from the skin or other areas		✓	

**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	
<b>Rare</b>	Low sodium level in the blood [symptoms of tiredness, weakness, confusion, combined with achy, stiff or uncoordinated muscles]		✓	
<b>Rare</b>	Gastrointestinal bleeding [vomiting blood or passing blood in stools]			✓
<b>Rare</b>	Seizures [loss of consciousness with uncontrollable shaking]			✓
<b>Rare</b>	Liver disorder [symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine]			✓
<b>Rare</b>	Serotonin syndrome [a combination of most or all of the following: confusion, restlessness, sweating, shaking, shivering, hallucinations, sudden jerking of the muscles, fast heartbeat]			✓
<b>See Warnings &amp; Precautions</b>	New or Worsened Emotional or Behavioural Problems			✓

*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 LUVOX at room temperature (15 – 25°C), in a dry place. Protect from light. Keep LUVOX out of reach of children. Keep container tightly closed. If your doctor tells you to stop taking LUVOX please return any leftover medicine to your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345  
 By toll-free fax: 866-678-6789  
 Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)  
 By email: [Canada\\_Vigilance@hc-sc.gc.ca](mailto:Canada_Vigilance@hc-sc.gc.ca)

By regular mail:  
 Canada Vigilance National Office  
 Marketed Health Products Safety and Effectiveness Information Bureau  
 Marketed Health Products Directorate  
 Health Products and Food Branch  
 Health Canada  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

*NOTE: Should you require information related to the management of the side effects, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.hc-sc.gc.ca> (Drug Product Database) or by contacting the sponsor, Abbott Laboratories Limited, at: 1-800-268-4276

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