

PART III: CONSUMER INFORMATION

^{Pr}FLUVOXAMINE – 50
^{Pr}FLUVOXAMINE – 100
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 FLUVOXAMINE. 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:

FLUVOXAMINE 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:

FLUVOXAMINE belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). FLUVOXAMINE 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 FLUVOXAMINE 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.
- currently taking or have recently taken tizanidine, mesoridazine, terfenadine, astemizole and cisapride.
- taking ramelteon, a medicine not available in Canada.

What the medicinal ingredient is:

Fluvoxamine maleate.

What the nonmedicinal ingredients are:

Carnauba wax, hydroxypropyl methylcellulose, magnesium stearate, mannitol, polydextrose, polyethylene glycol and titanium dioxide

What dosage forms it comes in:

FLUVOXAMINE is available as:

- 50 mg white tablets
- 100 mg 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.

FLUVOXAMINE 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. They may experience new or worsened feelings of agitation, hostility, anxiety, impulsivity, or thoughts about suicide, self-harm or harm to others. Suicidal thoughts and actions can occur in any age group but may be more likely in patients 18 to 24 years old. Should this happen to you, or those in your care, **consult your doctor immediately**. Close observation by a doctor is necessary in this situation. **Do not discontinue your medication on your own.**

Bone Fracture Risk

Taking FLUVOXAMINE 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.

BEFORE you use FLUVOXAMINE 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
- you have a bleeding disorder or have been told that you have low platelets
- you had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis
- you have glaucoma or increased pressure in your eyes
- any medications (prescription or nonprescription) 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

If you are already taking FLUVOXAMINE 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.

Some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer antidepressants, such as FLUVOXAMINE, during pregnancy have developed complications at birth requiring prolonged hospitalization, breathing support and tube feeding. Reported symptoms included: feeding and / or breathing difficulties, vomiting, seizures, tense or overly relaxed muscles, jitteriness, cyanosis (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 FLUVOXAMINE 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 FLUVOXAMINE if you are taking or have recently taken monoamine oxidase (MAO) inhibitors, methylene blue (intravenous), linezolid, thioridazine or pimozone.

FLUVOXAMINE 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, nonprescription 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, 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 FLUVOXAMINE.

PROPER USE OF THIS MEDICATION

Usual dose:

- It is very important that you take FLUVOXAMINE 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.
- FLUVOXAMINE 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 FLUVOXAMINE 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 FLUVOXAMINE 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 FLUVOXAMINE.

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. Take your medicine with you.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, FLUVOXAMINE 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 FLUVOXAMINE 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.

FLUVOXAMINE 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.

FLUVOXAMINE 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 FLUVOXAMINE. 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 after stopping or reducing the dosage of FLUVOXAMINE. 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 FLUVOXAMINE 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		✓	
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			✓
	Serotonin syndrome: a combination of most or all of the following: confusion, restlessness, sweating, shaking, shivering, hallucinations, sudden jerking of the muscles, fast heartbeat			✓
	Glaucoma: increased pressure in the eyes, eye pain and blurred vision		✓	
See Warnings & Precautions	New or Worsened Emotional or Behavioural Problems		✓	
	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 FLUVOXAMINE, contact your doctor or pharmacist.

HOW TO STORE IT

Store in a tightly closed container, in a dry place at temperatures between 15 – 30°C. Keep FLUVOXAMINE out of reach and sight of children. Keep container tightly closed. If your doctor tells you to stop taking FLUVOXAMINE, please return any leftover medicine to your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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