

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrFLUVOXAMINE-50

PrFLUVOXAMINE-100

Fluvoxamine Maleate Tablets, BP

Read this carefully before you start taking FLUVOXAMINE and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about FLUVOXAMINE.

What is FLUVOXAMINE used for?

FLUVOXAMINE is used in adults to relieve 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).

How does FLUVOXAMINE work?

FLUVOXAMINE 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. FLUVOXAMINE is thought to work by increasing the levels of serotonin in the brain.

What are the ingredients in FLUVOXAMINE?

Medicinal ingredients: Fluvoxamine maleate.

Non-medicinal ingredients:

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

FLUVOXAMINE comes in the following dosage forms:

FLUVOXAMINE is available as: 50 mg and 100 mg film-coated tablets

Do not use FLUVOXAMINE if you :

- are allergic to fluvoxamine maleate or any of the other ingredients in FLUVOXAMINE (**What are the ingredients in FLUVOXAMINE:**).
- 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).
- are going to have, or recently had methylene blue (a dye injected into a vein during surgery, x-rays or other imaging procedures).
- are currently taking or have recently taken other medicines used to treat mental health problems such as; thioridazine, mesoridazine, pimozide.

- are currently taking or have recently taken antihistamines used to treat allergies such as; terfenadine, astemizole.
- are currently taking or have recently taken cisapride, a medicine used to treat stomach problems.
- are currently taking or have recently taken tizanidine, a muscle relaxer used to treat spinal cord injury and multiple sclerosis (MS).
- are taking ramelteon, a sleep medicine not available in Canada.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FLUVOXAMINE. Talk about any health conditions or problems you may have, including if you:

- have heart, liver or kidney problems.
- have a history of seizures or fits.
- have a history or family history of mania/hypomania or bipolar disorder.
- have high or low blood sugar, or diabetes mellitus.
- have a bleeding disorder, bruise easily or have low levels of platelets in your blood.
- have low levels of sodium in your blood.
- have had a recent bone fracture, have osteoporosis or risk factors for osteoporosis.
- are breastfeeding. FLUVOXAMINE passes into breastmilk.
- have a history of alcohol or drug abuse.

Other warnings you should know about:

Changes in Feelings and Behaviour:

It is important that you have good communication with your healthcare professional 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 FLUVOXAMINE. 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 FLUVOXAMINE for any condition, and at any age, but it may be more likely in patients 18 to 24 years old. If this happens, tell your healthcare professional immediately. Do not stop taking FLUVOXAMINE on your own.

Effects on Pregnancy and Newborns:

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

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

If you take FLUVOXAMINE near the end of your pregnancy, you are at higher risk of heavy vaginal bleeding shortly after birth.

Some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer antidepressants, such as FLUVOXAMINE, during pregnancy have developed serious complications at

birth requiring prolonged hospitalization, breathing support and tube feeding. In most cases the drug was taken during the third trimester of pregnancy. 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. These symptoms usually began during the first 24 hours after the baby is born. If your baby has any of these symptoms talk to your healthcare professional immediately.

Effects on Fertility and Sexual Function:

Fertility in some men and women may be reduced while taking FLUVOXAMINE. In men, medicines like FLUVOXAMINE may affect your sperm. If you are trying to father a child while you are taking LUVOX, talk to your healthcare professional.

FLUVOXAMINE may also cause symptoms of sexual dysfunction. There have been reports of these symptoms lasting even after treatment with FLUVOXAMINE has ended. If this happens, talk to your healthcare professional.

Severe Skin Reactions:

Taking FLUVOXAMINE may cause serious skin reactions. This includes Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis. The risk is higher when you first start taking FLUVOXAMINE. **Stop taking FLUVOXAMINE and get immediate medical help if you have the following symptoms:**

- severe skin rash
- redness of the skin
- blistering of the lips, eyes or mouth
- peeling of the skin
- fever
- chills
- headache
- cough
- body aches

Bone Fractures and Osteoporosis:

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.

Angle-Closure Glaucoma:

FLUVOXAMINE can cause an acute attack of glaucoma. Having your eyes checked before you take FLUVOXAMINE could help identify if you are at risk of having angle-closure glaucoma. **Get immediate medical help if you have the following symptoms while taking FLUVOXAMINE:**

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

Discontinuation Symptoms:

Do **not** stop taking FLUVOXAMINE or change your dose without talking to your healthcare professional. 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) and others may occur suddenly after stopping or lowering your dose of FLUVOXAMINE. These symptoms might also happen if you miss a dose. Tell your healthcare professional immediately if you have these or any other symptoms.

Driving and Using Machines:

FLUVOXAMINE can make you feel sleepy. Do not drive or operate machinery until you know how you respond to FLUVOXAMINE.

Blood Tests:

FLUVOXAMINE can cause abnormal blood test results, including high levels of the hormone prolactin in your blood. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take FLUVOXAMINE if you are taking or have recently taken (in the last 14 days) any of the following drugs as you may have serious side effects:

- monoamine oxidase (MAO) inhibitor antidepressants (e.g. phenelzine sulphate, moclobemide) or a MAO inhibitor antibiotic (e.g. linezolid).
- methylene blue, a dye injected into a vein during surgery, x-rays or other imaging procedures.
- other medicines used to treat mental health problems such as; thioridazine, mesoridazine, pimozide.
- antihistamines, used to treat allergies such as; terfenadine, astemizole.
- cisapride, a medicine used to treat stomach problems.
- tizanidine, a muscle relaxer used to treat spinal cord injury and multiple sclerosis (MS).
- ramelteon, a sleep medicine not available in Canada.

The following may interact with FLUVOXAMINE:

- other antidepressants, such as SSRIs, SNRIs and certain tricyclics (e.g. bupropion, fluoxetine, paroxetine, clomipramine, imipramine, amitriptyline).
- other medicines that affect serotonin such as opioids, used to treat pain (e.g. tramadol, buprenorphine, tapentadol, meperidine, methadone, pentazocine, fentanyl (also used in anesthesia)) or used as substitution treatment in adults with problematic opioid use disorder (e.g. buprenorphine/naloxone), tryptophan and triptans (used to treat migraines).
- medicines used to treat schizophrenia, such as clozapine, olanzapine, quetiapine.
- medicines used to treat bipolar disorder, such as lithium.
- medicines used to treat epilepsy, such as phenytoin, carbamazepine, valproate/valproic acid.
- 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 medicines used to treat high blood pressure.
- medicines used to treat irregular heartbeat, such as quinidine, mexiletine.

- medicines used to treat diabetes.
- medicines used to treat some breathing problems, such as chronic obstructive pulmonary disease (COPD) or asthma (e.g., theophylline).
- medicines used to treat cough, such as dextromethorphan.
- medicines used to treat stomach problems, such as lansoprazole, omeprazole.
- sedatives, such as benzodiazapines (e.g. triazolam, midazolam, alprazolam, diazepam).
- cinacalcet, used to treat thyroid problems.
- tacrine, used to treat Alzheimer's Disease.
- cyclosporine, used to suppress the immune system.
- sildenafil, used to treat erectile dysfunction.
- bendamustine, a chemotherapy medicine used to treat cancer.
- diltiazem, used to treat chest pain.
- ropinirole, used to treat Parkinson's disease.
- St. John's Wort, an herbal medicine used to treat depression.
- alcohol. Do not drink alcohol while taking FLUVOXAMINE.
- caffeine. FLUVOXAMINE can increase the side effects from caffeine (tremor, palpitations, nausea, restlessness, insomnia).

How to take FLUVOXAMINE:

- Swallow FLUVOXAMINE tablets whole with water. Do not chew them.
- Take FLUVOXAMINE exactly how your healthcare professional has told you to. Your healthcare professional may change your dose gradually during treatment to find the dose that is right for you.
- 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. Continue to take FLUVOXAMINE for as long as your healthcare professional tells you to.
- Never increase or decrease your dose without talking to your healthcare professional.
- Do not suddenly stop taking FLUVOXAMINE without talking to your healthcare professional. Suddenly stopping FLUVOXAMINE or changing the dose may cause unpleasant side effects (see **Other warnings you should know about.**).

Usual dose:

- Depression: 100 mg to 200 mg per day.
- Obsessive-compulsive disorder: 100 mg to 300 mg per day.
- 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.

Overdose:

If you think you, or a person you are caring for, have taken too much FLUVOXAMINE, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

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.

What are possible side effects from using FLUVOXAMINE?

These are not all the possible side effects you may have when taking FLUVOXAMINE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- 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.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	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: seeing or hearing things that are not really there		✓	
UNKNOWN			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Low platelet levels in the blood: bruising or unusual bleeding from the skin or other areas		✓	
Stevens Johnson Syndrome/Toxic Epidermal Necrolysis (serious skin reactions): skin rash, redness of the skin, blistering of the lips, eyes or mouth, skin peeling, accompanied by fever, chills, headache, cough, body aches.			✓
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 problems: nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine			✓
Serotonin Toxicity/ 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			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
muscles, fast heartbeat, changes in blood pressure			
Glaucoma: eye pain, change in vision, swelling or redness in or around the eye			✓
Changes in feelings or behaviour: anger, anxiety, agitation, hostility		✓	
Thoughts of death or suicide			✓
High blood sugar: frequent urination, thirst and hunger		✓	
Low blood sugar: dizziness, lack of energy, drowsiness		✓	
Inflammation of the pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.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.

Storage:

Store in a dry place in well-closed containers at room temperature (15 °C to 30 °C). Protect from light.

Keep FLUVOXAMINE out of reach and sight of children. If your doctor tells you to stop taking FLUVOXAMINE, please return any leftover medicine to your pharmacist.

If you want more information about FLUVOXAMINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>). Find the Patient Medication Information by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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