

serotonin reuptake and these agents has been associated with an increased risk of bleeding (see **WARNINGS AND PRECAUTIONS-Warfarin and Other Drugs That Interfere With Hemostasis** [5.8]).

Because of the potential for the increased risk of serious adverse reactions including severe lowering of blood pressure and sedation when fluvoxamine and tizanidine are used together, fluvoxamine should not be used with tizanidine (see **WARNINGS AND PRECAUTIONS** [5.5]).

Because of the potential for the increased risk of serious adverse reactions when fluvoxamine and alosetron are used together, fluvoxamine should not be used with LotronexTM (alosetron) (see **WARNINGS AND PRECAUTIONS** [5.7]).

17.7 Alcohol

As with other psychotropic medications, patients should be advised to avoid alcohol while taking Fluvoxamine Maleate Tablets.

17.8 Allergic Reactions

Patients should be advised to notify their physicians if they develop a rash, hives, or a related allergic phenomenon during therapy with Fluvoxamine Maleate Tablets.

LotronexTM is a registered trademark of GlaxoSmithKline.

Manufactured by

ANI Pharmaceuticals, Inc
Baudette, MN 56623
Revised: 03/2011

17.9 FDA-Approved Medication Guide

MEDICATION GUIDE

Fluvoxamine (Flu VOX ah meen) Tablets

Read the Medication Guide that comes with Fluvoxamine Maleate Tablets before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

What is the most important information I should know about Fluvoxamine Maleate Tablets?

Fluvoxamine is the same kind of medicine as those used to treat depression and may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **Fluvoxamine Maleate Tablets and antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults within the **first few months of treatment or when the dose is changed**
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.

- Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when Fluvoxamine Maleate Tablets is started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

Tell your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. Fluvoxamine Maleate Tablets may be associated with these serious side effects:

2. Serotonin Syndrome or Neuroleptic Malignant Syndrome-like reactions. This condition can be life-threatening and may include:

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity

3. Severe allergic reactions:

- trouble breathing
- swelling of the face, tongue, eyes, or mouth
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

4. Abnormal bleeding: Fluvoxamine Maleate Tablets and antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin[®], Jantoven[®]), a non-steroidal anti-inflammatory drug (NSAID's, like ibuprofen, naproxen, or aspirin).

5. Seizures or convulsions

6. Manic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

7. Changes in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

8. Low salt (sodium) levels in the blood. Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

Do not stop Fluvoxamine Maleate Tablets without first talking to your healthcare provider.

Stopping Fluvoxamine Maleate Tablets too quickly may cause serious symptoms including:

- anxiety, irritability, high or low mood, feeling restless or changes in sleep habits
- headache, sweating, nausea, dizziness
- electric shock-like sensations, shaking, confusion

What is Fluvoxamine Maleate Tablets?

Fluvoxamine Maleate Tablets is a prescription medicine used to treat obsessive compulsive disorder (OCD). It is important to talk with your healthcare provider about the risks of treating OCD and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider.

Talk to your healthcare provider if you do not think that your condition is getting better with Fluvoxamine Maleate Tablets treatment.

Who should not take Fluvoxamine Maleate Tablets?

Do not take Fluvoxamine Maleate Tablets if you:

- are allergic to fluvoxamine maleate or any of the ingredients in Fluvoxamine Maleate Tablets. See the end of this Medication Guide for a complete list of ingredients in Fluvoxamine Maleate Tablets.
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
 - Do not take an MAOI within 2 weeks of stopping Fluvoxamine Maleate Tablets.
 - Do not start Fluvoxamine Maleate Tablets if you stopped taking an MAOI in the last 2 weeks.

People who take Fluvoxamine Maleate Tablets close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- high fever
- uncontrolled muscle spasms
- stiff muscles
- rapid changes in heart rate or blood pressure
- confusion
- loss of consciousness (pass out)
- **take Mellaril® (thioridazine). Do not take Mellaril® within 2 weeks of stopping FLUVOXAMINE MALEATE TABLETS because this can cause serious heart rhythm problems or sudden death.**
- **take Orap® (pimozide) because taking this drug with fluvoxamine maleate tablets can cause serious heart rhythm problems or sudden death.**
- **take Zanaflex® (tizanidine).** Fluvoxamine maleate tablets could increase the amount of Zanaflex in your body, which could increase its actions and side effects. This could include drowsiness and a drop in blood pressure and affecting how well you do things that require alertness.
- **Take Lotronex® (alosetron).** Fluvoxamine maleate tablets may increase the amount of Lotronex in your body, which could increase its actions and side effects.

What should I tell my healthcare provider before taking Fluvoxamine Maleate Tablets? Ask if you are not sure.

Before starting Fluvoxamine Maleate Tablets, tell your healthcare provider if you:

- Are taking certain drugs such as:

- **Monoamine oxidase inhibitors such as Emsam® (selegiline), Nardil® (phenelzine), or Parnate® (tranylcypromine)**
 - **Mellaril® (thioridazine): used to treat mental or mood problems**
 - **Zanaflex® (tizanidine): used to treat spasticity (a condition in which muscles keep tightening and cramping)**
 - **Orap® (pimozide): used to treat Tourette Syndrome (a brain condition causing tics)**
 - **Lotronex® (alosetron): used to treat a condition with diarrhea, continuing stomach pain, cramps, and bloating**
 - Triptans: used to treat migraine headache
 - Medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, SSRIs, SNRIs, or antipsychotics
 - Tramadol: used to reduce pain
 - Benzodiazepines: used to reduce anxiety, stress, emotional upset, or seizures; helps you sleep; helps with alcohol withdrawal; reduces restlessness; and relaxes muscles
 - Methadone: used to relieve pain or to help with addiction
 - Clozapine: used to treat mental disorders.
 - Mexiletine: used to treat abnormalities in heart rhythm.
 - Theophylline used to treat swollen air passages in your lungs, to relax the muscles in your chest to ease shortness of breath, often to treat asthma
 - Warfarin and other drugs that affect how your blood clots
 - Diuretics to treat high blood pressure, congestive heart failure, or swelling
 - Over-the-counter supplements such as tryptophan or St. John's Wort
- have liver problems
 - have kidney problems
 - have heart problems
 - have or had seizures or convulsions
 - have bipolar disorder or mania
 - have low sodium levels in your blood
 - have a history of a stroke
 - have high blood pressure
 - have or had bleeding problems
 - are pregnant or plan to become pregnant. It is not known if Fluvoxamine Maleate Tablets will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating OCD during pregnancy.
 - are breast-feeding or plan to breast-feed. Some Fluvoxamine Maleate Tablets may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking Fluvoxamine Maleate Tablets.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Fluvoxamine Maleate Tablets and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Your healthcare provider or pharmacist can tell you if it is safe to take Fluvoxamine Maleate Tablets with your other medicines. Do not start or stop any medicine while taking Fluvoxamine Maleate Tablets without talking to your healthcare provider first.

If you take Fluvoxamine Maleate Tablets, you should not take any other medicines that contain fluvoxamine including: LUVOX CR®

How should I take Fluvoxamine Maleate Tablets?

- Take Fluvoxamine Maleate Tablets exactly as prescribed. Your healthcare provider may need to change the dose of Fluvoxamine Maleate Tablets until it is the right dose for you.
- Fluvoxamine Maleate Tablets may be taken with or without food.
- If you miss a dose of Fluvoxamine Maleate Tablets, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of Fluvoxamine Maleate Tablets at the same time.
- If you take too much Fluvoxamine Maleate Tablets, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking Fluvoxamine Maleate Tablets?

Fluvoxamine Maleate Tablets can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how Fluvoxamine Maleate Tablets affects you. Do not drink alcohol while using Fluvoxamine Maleate Tablets.

What are the possible side effects of Fluvoxamine Maleate Tablets?

Fluvoxamine Maleate Tablets may cause serious side effects, including:

- See “What is the most important information I should know about Fluvoxamine Maleate Tablets?”
- **Feeling anxious or trouble sleeping**

Common possible side effects in people who take Fluvoxamine Maleate Tablets include::

- nausea
- sleepiness
- weakness
- indigestion
- sweating
- loss of appetite
- shaking
- vomiting
- delayed ejaculation
- inability to have an orgasm
- decreased sex drive
- dry mouth
- stuffy nose
- unusual taste
- frequent urination

Other side effects in children and adolescents include:

- agitation or abnormal increase in activity
- feeling depressed or sad
- excessive gas
- heavy menstrual periods
- rash
- possible slowed growth rate and weight change.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Fluvoxamine Maleate Tablets. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO PROSAR Inc at 1-800-308-6755 or FDA AT 1-800-FDA-1088.

How should I store Fluvoxamine Maleate Tablets?

Store Fluvoxamine Maleate Tablets at room temperature between 59°F to 86°F (15°C to 30°C).

- Keep Fluvoxamine Maleate Tablets away from high humidity.
- Keep FLUVOXAMINE MALEATE TABLETS bottle closed tightly.

Keep Fluvoxamine Maleate Tablets and all medicines out of the reach of children.

General information about Fluvoxamine Maleate Tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Fluvoxamine Maleate Tablets for a condition for which it was not prescribed. Do not give Fluvoxamine Maleate Tablets to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about Fluvoxamine Maleate Tablets. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about Fluvoxamine Maleate Tablets that is written for healthcare professionals.

For more information about Fluvoxamine Maleate Tablets call [PROSAR](http://www.prosar.com) Inc at 1-800-308-6755 or go to www.anipharma.com

What are the ingredients in Fluvoxamine Maleate Tablets?

Active ingredient: Fluvoxamine maleate

Inactive ingredients:

Tablets 25mg: carnauba wax, hydroxypropyl methylcellulose, mannitol, polyethylene glycol, polysorbate 80, pregelatinized starch (potato), silicon dioxide, sodium stearyl fumarate, starch (corn), and titanium dioxide..

Tablets 50mg and 100mg: In addition to the above inactive ingredients, contain synthetic iron oxides.

Manufactured by:

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Baudette, MN 56623

Rev 03/2011

This Medication Guide has been approved by the U.S. Food and Drug Administration.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
03/16/2011