MEDICATION GUIDE

Fluvoxamine Maleate Extended-Release Capsules

Read the Medication Guide that comes with fluvoxamine maleate extended-release capsules 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 to 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 extended-release capsules?

Fluvoxamine maleate extended-release capsules are the same kind of medicine as those used to treat depression. These medicines may cause serious side effects, including:

1. **Suicidal thoughts or actions:**

- **Fluvoxamine maleate extended-release capsules and other 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 extended-release capsules 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 in 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

Call your healthcare provider right away if you have any of the following symptoms, or call 911 in an emergency. Fluvoxamine maleate extended-release capsules may be associated with these serious side effects:

2. **Serotonin Syndrome. 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. **Visual Problems**

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

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

4. **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

5. **Abnormal bleeding**: Fluvoxamine maleate extended-release capsules and other 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 (NSAIDs, like ibuprofen or naproxen), or aspirin.
6. **Seizures or convulsions**
7. **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

8. **Changes in appetite or weight.** Children and adolescents should have height and weight monitored during treatment.
9. **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 taking fluvoxamine maleate extended-release capsules without first talking to your healthcare provider. Stopping fluvoxamine maleate extended-release capsules 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 are fluvoxamine maleate extended-release capsules?

Fluvoxamine maleate extended-release capsules are a prescription medicine used to treat obsessive compulsive disorder (OCD). It is the same kind of drug that is used to treat depression. 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 extended-release capsules treatment.

Who should not take fluvoxamine maleate extended-release capsules?

Do not take fluvoxamine maleate extended-release capsules if you:

- are allergic to fluvoxamine maleate or any of the ingredients in fluvoxamine maleate extended-release capsules. See the end of this Medication Guide for a complete list of ingredients in fluvoxamine maleate extended-release capsules.
- 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 extended-release capsules unless directed to do so by your physician.
- Do not start fluvoxamine maleate extended-release capsules if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take fluvoxamine maleate extended-release capsules 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). Mellaril® should not be taken with fluvoxamine maleate extended-release capsules because this can cause serious heart rhythm problems or sudden death.**
- **take Zanaflex® (tizanidine) because fluvoxamine maleate extended-release capsules can increase the amount of Zanaflex in your body, which could increase its actions and side effects. This could include causing drowsiness and a drop in blood pressure and affecting how well you do things that require alertness.**
- **take the antipsychotic medicine Orap® (pimozide) because this can cause serious heart problems.**
- **Take Lotronex® (alosetron) because fluvoxamine maleate extended-release capsules can increase the amount of Lotronex in your body, which could increase its actions and side effects.**
- **take Rozerem® (ramelteon) because fluvoxamine maleate extended-release capsules can increase the amount of Rozerem in your body, which could increase its actions and side effects.**

What should I tell my healthcare provider before taking fluvoxamine maleate extended-release capsules? Ask if you are not sure.

Before starting fluvoxamine maleate extended-release capsules, tell your healthcare provider if you:

- are taking certain drugs such as:
- Clozaril®(clozapine): used to treat schizophrenia
- Mexitil®(mexiletine): used to treat problems with heart rhythm
- 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
- 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 extended-release capsules will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating obsessive compulsive disorder (OCD) during pregnancy
- are breast-feeding or plan to breast-feed. Some fluvoxamine maleate extended-release capsules may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking fluvoxamine maleate extended-release capsules.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Fluvoxamine maleate extended-release capsules 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 extended-release capsules with your other medicines. Do not start or stop any medicine while taking fluvoxamine maleate extended-release capsules without talking to your healthcare provider first.

If you take fluvoxamine maleate extended-release capsules, you should not take any other medicines that contain fluvoxamine maleate including: Fluvoxamine Maleate Immediate-Release Tablets.

How should I take fluvoxamine maleate extended-release capsules?

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Take fluvoxamine maleate extended-release capsules at night exactly as prescribed. Your healthcare provider may need to change the dose of fluvoxamine maleate extended-release capsules until it is the right dose for you.

- Fluvoxamine maleate extended-release capsules may be taken with or without food.
- If you miss a dose of fluvoxamine maleate extended-release capsules, 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 extended-release capsules at the same time.
- If you take too much fluvoxamine maleate extended-release capsules, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking fluvoxamine maleate extended-release capsules?

Fluvoxamine maleate extended-release capsules 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 extended-release capsules affect you. Do not drink alcohol while using fluvoxamine maleate extended-release capsules.

What are the possible side effects of fluvoxamine maleate extended-release capsules?

Fluvoxamine maleate extended-release capsules may cause serious side effects, including all of those described in the section entitled "What is the most important information I should know about fluvoxamine maleate extended-release capsules?"

Common possible side effects in people who take fluvoxamine include**:**

- Nausea
- Sleepiness
- Weakness
- Dizziness
- Feeling anxious
- Trouble sleeping
- Sexual problems
- Sweating
- Shaking
- Not feeling hungry
- Dry mouth
- Diarrhea
- Muscle pain
- Sore throat
- Throwing up
- Upset stomach
- Yawning

Other side effects in children and adolescents taking fluvoxamine include:

- abnormal increase in muscle movement or agitation
- depression
- heavy menstrual periods
- flatulence (gas)
- rash

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 extended-release capsules. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO FDA AT 1-800-FDA-1088.

How should I store fluvoxamine maleate extended-release capsules?

- Store fluvoxamine maleate extended-release capsules at 20º to 25°C (68º to 77°F). [see USP Controlled Room Temperature].
- Keep fluvoxamine maleate extended-release capsules away from high temperatures (above 86°F or 30°C) and high humidity (dampness).
- Keep the fluvoxamine maleate extended-release capsules bottle closed tightly.

Keep fluvoxamine maleate extended-release capsules and all medicines out of the reach of children.

General information about fluvoxamine maleate extended-release capsules Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use fluvoxamine maleate extended-release capsules for a condition for which it was not prescribed. Do not give fluvoxamine maleate extended-release capsules 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 extended-release capsules. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about fluvoxamine maleate extended-release capsules that is written for healthcare professionals.

What are the ingredients in fluvoxamine maleate extended-release capsules?

Active ingredient: fluvoxamine maleate

Inactive ingredients:

- **Extended-Release Capsules**: black iron oxide, dehydrated alcohol, ethylcellulose, gelatin, hydroxypropyl cellulose, isopropyl alcohol, povidone, shellac, sugar spheres, talc, titanium dioxide, triethyl citrate, D&C Red No. 28, and FD&C Blue No. 1.

The 100 mg strength also contains FD&C Blue No. 2, FD&C Red No. 40 and D&C Yellow No. 10.

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

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Spring Valley, NY 10977

R10/14 OS175A-01-1-04