



Patient Information Sheet

Fluvoxamine maleate

This is a summary of the most important information about fluvoxamine. For details, talk to your healthcare professional.

FDA ALERT [07/2005] – Suicidal Thoughts or Actions in Children and Adults

Patients with depression or other mental illnesses often think about or attempt suicide. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior (or their care givers) should contact their healthcare professional right away.

Children

Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. FDA has approved fluvoxamine for treating children only if they have obsessive-compulsive disorder.

Adults

Several recent scientific publications report the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications. Even before these reports became available, FDA began a complete review of all available data to determine whether there is an increased risk of suicidal thinking or behavior in adults being treated with antidepressant medications. It is expected that this review will take a year or longer to complete. In the meantime, FDA is highlighting that adults being treated with antidepressant medication, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Is Fluvoxamine?

Fluvoxamine is in a class of medicines called selective serotonin reuptake inhibitors (SSRIs). Fluvoxamine is used to treat obsessive-compulsive disorder (OCD).

Who Should Not Take Fluvoxamine?

- **Never take fluvoxamine if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking fluvoxamine close in time to an MAOI can result in serious, sometimes fatal, reactions, including:**

- **High body temperature**
- **Coma**
- **Seizures (convulsions)**

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

- **Never take fluvoxamine if you take the following medicines because it can result in serious heart beat problems.**
 - **Mellaril (thioridazine)**, a drug to treat schizophrenia
 - **Orap (pimozide)**, a drug to treat Tourette's disorder

What Are The Risks?

- **Suicidal thoughts or actions:** See FDA Alert.
- **Stopping fluvoxamine:** Do not stop taking fluvoxamine suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **Bleeding problems:** Fluvoxamine may cause bleeding problems, especially if taken with aspirin, NSAIDs (nonsteroidal anti-inflammatory drugs, such as ibuprofen or naproxen), or other drugs that affect bleeding.
- **Mania:** You may become unusually hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion), even if you are not taking fluvoxamine close in time with a MAOI.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because babies delivered to mothers taking fluvoxamine late in pregnancy have developed problems, such as difficulty breathing and feeding.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Other side effects** include nausea, vomiting, upset stomach, difficulty sleeping, nervousness, shakiness, sweating, weakness, decreased appetite, and sleepiness.
- **Tell your healthcare professional** about all your medical conditions, especially if you have liver disease. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Drugs or Foods?

- Fluvoxamine may interact with medicines other than the ones already mentioned in this information sheet. These interactions can cause serious side effects. Of special concern are:
 - Certain benzodiazepines, which treat anxiety
 - Mexilitil (mexiletine), which treats heart beat problems
 - Theophylline, which treats asthma
 - Warfarin, which treats blood clotsTell your healthcare professional about all medicines, vitamins, and herbal supplements you take.

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@cder.fda.gov





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- If you plan to drink alcohol, talk to your healthcare professional.

How Do I Take Fluvoxamine?

Fluvoxamine is taken by mouth, with or without food, exactly as prescribed by your healthcare professional.

Is There Anything Else I Need to Know?

You can get more information about antidepressants at:
<http://www.fda.gov/cder/drug/antidepressants/default.htm>

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