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Fluvoxamine

pronounced as (floo vox' a meen)

IMPORTANT WARNING:

A small number of children, teenagers, and young adults (up to 24 years of age) who took antidepressants ('mood elevators') such as fluvoxamine during clinical studies became suicidal (thinking about harming or killing oneself or planning or trying to do so). Children, teenagers, and young adults who take antidepressants to treat depression or other mental illnesses may be more likely to become suicidal than children, teenagers, and young adults who do not take antidepressants to treat these conditions. However, experts are not sure about how great this risk is and how much it should be considered in deciding whether a child or teenager should take an antidepressant.

You should know that your mental health may change in unexpected ways when you take fluvoxamine or other antidepressants even if you are an adult over 24 years of age. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep or staying asleep; aggressive behavior; irritability; acting without thinking; severe restlessness; and frenzied abnormal excitement. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.

Your healthcare provider will want to see you often while you are taking fluvoxamine, especially at the beginning of your treatment. Be sure to keep all appointments for office visits with your doctor.

The doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with fluvoxamine. Read the information carefully and ask your doctor or pharmacist if you have any questions. You also can obtain the Medication Guide from the FDA website: <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>].

No matter your age, before you take an antidepressant, you, your parent, or your caregiver should talk to your doctor about the risks and benefits of treating your condition with an antidepressant or

with other treatments. You should also talk about the risks and benefits of not treating your condition. You should know that having depression or another mental illness greatly increases the risk that you will become suicidal. This risk is higher if you or anyone in your family has or has ever had bipolar disorder (mood that changes from depressed to abnormally excited) or mania (frenzied, abnormally excited mood) or has thought about or attempted suicide. Talk to your doctor about your condition, symptoms, and personal and family medical history. You and your doctor will decide what type of treatment is right for you.

Why is this medication prescribed?

Fluvoxamine is used to treat obsessive-compulsive disorder (bothersome thoughts that won't go away and the need to perform certain actions over and over) and social anxiety disorder (extreme fear of interacting with others or performing in front of others that interferes with normal life). Fluvoxamine is in a class of medications called selective serotonin reuptake inhibitors (SSRIs). It works by increasing the amount of serotonin, a natural substance in the brain that helps maintain mental balance.

How should this medicine be used?

Fluvoxamine comes as a tablet and an extended-release capsule to take by mouth. The tablet usually is taken either once daily at bedtime or twice daily, once in the morning and once at bedtime. The extended-release capsule usually is taken, with or without food, once daily at bedtime. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take fluvoxamine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the extended-release capsules whole; do not be crush or chew them.

Your doctor may start you on a low dose of fluvoxamine and gradually increase your dose, not more often than once every week, depending on how well the medication works for you and the side effects you experience.

It may take several weeks or longer for you to feel the full benefit of fluvoxamine. Continue to take fluvoxamine even if you feel well. Do not stop taking fluvoxamine without talking to your doctor. If you suddenly stop taking fluvoxamine, you may experience withdrawal symptoms such as irritability; agitation; dizziness; extreme worry; uneasiness; confusion; headache; tiredness; mood changes; difficulty falling asleep or staying asleep; or pain, burning, numbness, tingling or 'electric shock' sensations in the hands or feet. Your doctor probably will decrease your dose gradually.

Other uses for this medicine

Fluvoxamine is also used sometimes to treat depression. Talk with your doctor about the possible risks of using this medication for your condition.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking fluvoxamine,

- tell your doctor and pharmacist if you are allergic to fluvoxamine, any other medications, or any of the ingredients in fluvoxamine tablets and extended-release capsules. Ask your doctor or pharmacist for a list of the ingredients..
- tell your doctor if you are taking alosetron (Lotronex), pimozide (Orap), ramelteon (Rozerem), tizanidine (Zanaflex), or thioridazine. Your doctor will probably tell you not to take fluvoxamine.
- tell your doctor if you are taking the following medications or if you have stopped taking them within the past 14 days: monoamine oxidase (MAO) inhibitors such as isocarboxazid (Marplan), linezolid (Zyvox), methylene blue; phenelzine (Nardil), rasagiline (Azilect), selegiline (Emsam, Zelapar), and tranylcypromine (Parnate). Your doctor will probably tell you not to take fluvoxamine. If you stop taking fluvoxamine, you should wait at least 14 days before you start to take an MAO inhibitor.
- tell your doctor and pharmacist what prescription and nonprescription medications, and vitamins you are taking or plan to take. Be sure to mention any of the following: alprazolam (Xanax); amphetamines; anticoagulants ('blood thinners') such as warfarin (Coumadin); aspirin or aspirin-containing products and other nonsteroidal anti-inflammatory drugs such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn); beta-blockers such as metoprolol (Lopressor, Toprol) and propranolol (Hemangeol, Inderal, Innopran); buspirone; carbamazepine (Carbatrol, Equetro, Tegretol, others); clozapine (Clozaril, Versacloz); cyclosporine (Neoral, Sandimmune); dextromethorphan (in cough medications); diazepam (Valium, Valtoco); diltiazem (Cardizem, Cartia, Tiazac, others); diuretics ('water pills'); fentanyl (Abstral, Actiq, Fentora, Onsolis, others); haloperidol (Haldol); ketoconazole; lithium (Lithobid); medications for migraine headaches such as almotriptan (Axert), eletriptan (Relpax), frovatriptan (Frova), naratriptan, rizatriptan (Maxalt), sumatriptan (Imitrex), and zolmitriptan (Zomig); methadone (Methadose); mexiletine; metoclopramide; midazolam (Seizalam); omeprazole (Prilosec, Zegerid); other medications for anxiety, depression, or mental illness; phenytoin (Dilantin, Phenytek); tacrine (Cognex); theophylline (Theo-24, Theochron); tramadol (Conzip, Qdolo, Ultram, in Ultracet); triazolam (Halcion); and quinidine. Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with fluvoxamine, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products and nutritional supplements you are taking, especially products that contain St. John's wort and tryptophan.
- tell your doctor if you drink or have ever drunk large amounts of alcohol or have used street drugs or have overused prescription medications. Also tell your doctor if you have recently had a heart attack, if you have low sodium levels in the blood; or if you have or have ever had bleeding problems; seizures; or heart, kidney, or liver disease.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, or if you plan to become pregnant or are breast-feeding. If you become pregnant while taking fluvoxamine, call your doctor. Fluvoxamine may cause problems in newborns following delivery if it is taken during the last months of pregnancy.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking fluvoxamine.
- you should know that this medication may make you drowsy or affect your judgment, thinking, or motor skills. Do not drive a car or operate machinery until you know how this medication affects you.
- remember that alcohol can add to the drowsiness caused by this medication. You should not drink alcohol while taking fluvoxamine.

- tell your doctor if you use tobacco products. Cigarette smoking may decrease the effectiveness of this medication.
- you should know that fluvoxamine may cause angle-closure glaucoma (a condition where the fluid is suddenly blocked and unable to flow out of the eye causing a quick, severe increase in eye pressure which may lead to a loss of vision). Talk to your doctor about having an eye examination before you start taking this medication. If you have nausea, eye pain, changes in vision, such as seeing colored rings around lights, and swelling or redness in or around the eye, call your doctor or get emergency medical treatment right away.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Fluvoxamine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- drowsiness
- dry mouth
- nausea
- vomiting
- diarrhea
- stomach pain
- constipation
- indigestion
- gas
- change in taste
- stuffy nose
- decreased appetite
- sweating
- difficulty falling asleep or staying asleep
- weight loss
- nervousness

- sexual problems in males; decreased sex drive, inability to get or keep an erection, or delayed or absent ejaculation
- sexual problems in females; decreased sex drive, or delayed orgasm or unable to have an orgasm

Some side effects can be serious. If you experience any of the following symptoms, or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, call your doctor immediately or get emergency medical treatment:

- dizziness
- fever, sweating, confusion, fast or irregular heartbeat, and severe muscle stiffness or twitching, agitation, hallucinations, loss of coordination, nausea, vomiting, or diarrhea
- pain, burning, numbness, or tingling in the hands or feet
- shaking of a part of the body that you cannot control
- headache
- difficulty concentrating
- difficulty concentrating, memory problems, or confusion
- weakness
- unsteadiness
- rash
- hives
- swelling of the eyes, face, lips, tongue, or throat
- slowed or difficult breathing
- seizures
- loss of consciousness
- unusual bleeding or bruising
- bloody nose
- vomiting blood or a material that looks like coffee grounds
- red blood in stool or black and tarry stools

Fluvoxamine may decrease appetite and cause weight loss in children. Your child's doctor will watch his or her growth carefully. Talk to your child's doctor if you have concerns about your child's growth or weight while he or she is taking this medication. Talk to your child's doctor about the risks of giving fluvoxamine to your child.

Fluvoxamine may cause other side effects. Call your doctor if you have any unusual problems while you are taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online

(<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- drowsiness
- agitation, hallucinations, fever, sweating, confusion, fast heartbeat, shivering, severe muscle stiffness or twitching, loss of coordination, nausea, vomiting, or diarrhea
- excessive tiredness
- dizziness
- agitation
- mania
- seizures
- loss of consciousness

What other information should I know?

It is important to keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your response to fluvoxamine.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Luvox[®]
- Luvox[®] CR

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