

Brightside Specialty Pharmacy

431 N. Tustin Ave., STE C, Santa Ana, CA 92705

Phone 714-707-5115

Date :8/15/2022

Patient Education for FLUVOXAMINE MALEATE 100 MG TAB



Compliance important even during symptom-free periods Avoid taking with other CNS depressant drugs or alcohol Many drug-drug interactions possible with this drug May cause drowsiness or dizziness Use caution driving. Worsening depression/thoughts of suicide should be reported ASAP Dispense & explain patient package insert and medication guide. Discuss gradual dose reduction with MD before stopping medication May cause problems in newborns. Use with caution in 3rd trimester

Take doses regularly, even when feeling well Avoid alcohol/other drugs that make you sleepy Review all drugs you are taking with your doctor May make you drowsy or dizzy. Drive with caution Immediately report to MD any thoughts of suicide. Important to read patient package insert& med guide MD may need to reduce the dose before you stop it. Discuss risk vs benefits of use during pregnancy.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

FLUVOXAMINE - ORAL

(floo-VOX-a-meen)

COMMON BRAND NAME(S):

Luvox

WARNING:

Antidepressant medications are used to treat a variety

of conditions, including depression and other mental/mood disorders. These medications can help prevent suicidal thoughts/attempts and provide other important benefits. However, studies have shown that a small number of people (especially people younger than 25) who take antidepressants for any condition may experience worsening depression, other mental/mood symptoms, or suicidal thoughts/attempts. It is very important to talk with the doctor about the risks and benefits of antidepressant medication (especially for people younger than 25), even if treatment is not for a mental/mood condition.

Tell the doctor right away if you notice worsening depression/other psychiatric conditions, unusual behavior changes (including possible suicidal thoughts/attempts), or other mental/mood changes (including new/worsening anxiety, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, very rapid speech). Be especially watchful for these symptoms when a new antidepressant is started or when the dose is changed.

USES:

Fluvoxamine is used to treat obsessive-compulsive disorder

(OCD). It helps decrease thoughts that are unwanted or that don't

go away (obsessions), and it helps to reduce the urge to perform repeated tasks (compulsions such as hand-washing, counting, checking) that interfere with daily living. Fluvoxamine is known as a selective serotonin reuptake inhibitor (SSRI). This medication works by helping to restore the balance of a certain natural substance (serotonin) in the brain.

OTHER USES:

This section contains uses of this drug that are not

listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This drug may also be used for anxiety disorders, depression, post-traumatic stress disorder, or binge eating disorder (BED).

HOW TO USE:

Read the Medication Guide and, if available, the

Patient Information Leaflet provided by your pharmacist before you start taking fluvoxamine and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth with or without food as directed by your doctor, usually once daily at bedtime, or twice daily (once in the morning and once at bedtime). If you are taking this medication twice daily and the doses are not equal, then the larger of the 2 doses should be taken at bedtime.

The dosage is based on your medical condition, response to treatment, age, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). In children, the dosage may also be based on their age and gender. To reduce your risk of side effects, your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully.

Do not increase your dose or use this drug more often or for longer than prescribed. Your condition will not improve any faster, and your risk of side effects will increase. Take this medication regularly to get the most benefit from it. To help you remember, take it at the same time(s) each day.

Keep taking this medication even if you feel well. Do not stop

taking this medication without consulting your doctor. Some conditions may become worse when this drug is suddenly stopped. Also, you may experience symptoms such as mood swings, headache, tiredness, sleep changes, and brief feelings similar to electric shock. To prevent these symptoms while you are stopping treatment with this drug, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details. Report any new or worsening symptoms right away.

It may take up to several weeks before you get the full benefit of this drug.

Tell your doctor if your condition does not improve or if it worsens.

SIDE EFFECTS:

See also Warning section.

Nausea, vomiting, drowsiness, dizziness, loss of appetite, trouble sleeping, weakness, and sweating may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: easy bleeding/bruising, shaking (tremor), decreased interest in sex, changes in sexual ability.

Get medical help right away if you have any very serious side effects, including: fainting, irregular heartbeat, black stools, vomit that looks like coffee grounds, seizures, eye pain/swelling/redness, widened pupils, vision changes (such as seeing rainbows around lights at night, blurred vision).

This medication may increase serotonin and rarely cause a very serious condition called serotonin syndrome/toxicity. The risk increases if you are also taking other drugs that increase serotonin, so tell your doctor or pharmacist of all the drugs you take (see Drug Interactions section). Get medical help right away if you develop some of the following symptoms: fast heartbeat, hallucinations, loss of coordination, severe dizziness, severe nausea/vomiting/diarrhea, twitching muscles, unexplained fever, unusual restlessness.

Rarely, males may have a painful or prolonged erection lasting 4 or more hours. If this occurs, stop using this drug and get medical help right away, or permanent problems could occur.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at

1-866-234-2345.

PRECAUTIONS:

Before taking fluvoxamine, tell your doctor or

pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: personal or family history of bipolar/manic-depressive disorder, personal or family history of suicide attempts, liver problems, seizures, low sodium in the blood, bleeding problems, personal or family history of glaucoma (angle-closure type).

This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

Fluvoxamine may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away.

The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using fluvoxamine, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death).

Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics "water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using fluvoxamine safely.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Older adults may be more sensitive to the side effects of this drug, especially bleeding, or loss of coordination, QT prolongation. Older adults may also be more likely to develop a type of salt imbalance (hyponatremia), especially if they are taking "water pills" (diuretics). Loss of coordination can increase the risk of falling.

Children may be more sensitive to the side effects of this drug, especially loss of appetite and weight loss. Monitor weight and height in children who are taking this drug.

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Also, babies born to mothers who have used this drug during the last 3 months of pregnancy may rarely develop withdrawal symptoms such as feeding/breathing difficulties, seizures, muscle stiffness, or constant crying. If you notice any of these symptoms in your newborn, tell the doctor promptly.

Since untreated mental/mood problems (such as depression,

obsessive compulsive disorder, post-traumatic stress disorder) can be a serious condition, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately discuss with your doctor the benefits and risks of using this medication during pregnancy.

This drug passes into breast milk and may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects.

This document does not contain all possible drug interactions.

Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug are: other drugs that can cause bleeding/bruising (including antiplatelet drugs such as clopidogrel, NSAIDs such as ibuprofen/naproxen, "blood thinners" such as dabigatran/warfarin).

Aspirin can increase the risk of bleeding when used with this medication. However, if your doctor has directed you to take low-dose aspirin for heart attack or stroke prevention (usually 81-162 milligrams a day), you should continue taking it unless your doctor instructs you otherwise. Ask your doctor or pharmacist for more details.

Many drugs besides fluvoxamine may affect the heart rhythm (QT prolongation), including pimozide, thioridazine, among others.

This medication can slow down the removal of other medications from your body, which may affect how they work. Examples of affected drugs include alosetron, clozapine, methadone, melatonin, ramelteon, tacrine, tizanidine, certain benzodiazepines such as alprazolam/diazepam/triazolam, certain beta-blockers such as metoprolol/propranolol, tricyclic antidepressants such as imipramine, among others.

Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before and after treatment with this medication. Ask your doctor when to start or stop taking this medication.

The risk of serotonin syndrome/toxicity increases if you are also taking other drugs that increase serotonin. Examples include street drugs such as MDMA/"ecstasy," St. John's wort, certain antidepressants (including other SSRIs such as fluoxetine/paroxetine, SNRIs such as duloxetine/venlafaxine), tryptophan, among others. The risk of serotonin syndrome/toxicity may be more likely when you start or increase the dose of these drugs.

This medication can increase the effects of caffeine. Avoid drinking large amounts of beverages containing caffeine (coffee, tea, colas) or eating large amounts of chocolate or taking nonprescription products that contain caffeine.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, marijuana (cannabis), antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants, and opioid pain relievers (such as codeine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

Cigarette smoking decreases blood levels of this medication. Tell your doctor if you smoke or if you have recently stopped smoking.

This medication may interfere with certain medical/laboratory tests (including brain scan for Parkinson's disease), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: fast/slow/irregular heartbeat, trouble breathing, seizures.

NOTES:

Do not share this medication with others.

Keep all regular medical and psychiatric appointments.

MISSED DOSE:

If you miss a dose, take it as soon as you

remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Information last revised May 2022.

Copyright(c) 2022 First Databank, Inc.