

Patient Education

FLUOXETINE - ORAL

IMPORTANT NOTE: The following information is intended to supplement, not substitute for, the expertise and judgment of your physician, pharmacist or other healthcare professional. It should not be construed to indicate that use of the drug is safe, appropriate, or effective for you. Consult your healthcare professional before using this drug.

FLUOXETINE - ORAL

(flew-OX-eh-teen)

COMMON BRAND NAME(S): Prozac, Sarafem

USES:

Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) used to treat depression, obsessive-compulsive disorder, panic attacks, certain eating disorders (bulimia), and a severe form of premenstrual syndrome (premenstrual dysphoric disorder or PMDD).

This medication works by restoring the balance of natural substances (neurotransmitters) in the brain, thereby improving mood and feelings of well-being.

OTHER USES:

This drug is also used to treat certain other eating disorders (anorexia nervosa), obesity, and depression associated with bipolar disorder.

HOW TO USE:

Take this medication by mouth usually once a day in the morning, with or without food, or as directed by your doctor. If your doctor tells you to take this medication twice a day, take a dose in the morning and at noon. Dosage is based on your medical condition and response to therapy.

Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day.

It is important to continue taking this medication even if you feel well. Do not stop taking this medication without consulting your doctor.

Do not take more or less medication than prescribed. The maximum recommended dose for adults treated for obsessive-compulsive disorder and premenstrual dysphoric disorder is 80 mg per day. The maximum recommended dose for children with attention-deficit hyperactivity disorder (ADHD) treated for depression is 20 mg per day.

It may take 4 weeks or longer before the full benefit of this drug takes effect. Inform your doctor if your condition persists or worsens.

SIDE EFFECTS:

Nausea, loss of appetite, diarrhea, dry mouth, trouble sleeping, dizziness, drowsiness, yawning, weakness, or sweating may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Tell your doctor immediately if any of these serious side effects occur: unusual or severe mental/mood changes (e.g., anxiety, mania), weight loss, change in sexual desire and ability, vision changes.

Tell your doctor immediately if any of these unlikely but serious side effects occur: uncontrolled movements (tremor), fever/flu-like symptoms.

Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: unusual muscle stiffness, fast/irregular heartbeats, chest pain, black stools, vomit that looks like coffee grounds, easy bruising/bleeding, unusual bleeding, seizures.

For males, in the very unlikely event you have a painful, prolonged erection (lasting more than 4 hours), stop using this drug and seek immediate medical attention or permanent problems could occur.

A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing.

If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS:

Before taking fluoxetine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, kidney disease, stomach bleeding, diabetes, seizure disorder.

Though uncommon, depression can lead to thoughts or attempts of suicide. Tell your doctor immediately if you have any suicidal thoughts, worsening depression, or any other mental/mood changes (including new or worsening anxiety, agitation, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, rapid speech). Keep all medical appointments so your healthcare professional can monitor your progress closely and adjust/change your medication if needed.

If you have diabetes, fluoxetine may affect your blood glucose levels. Monitor your blood glucose regularly, and share the results with your doctor. The dose of your anti-diabetic medication(s) may need to be adjusted.

Liquid preparations of this product may contain sugar and/or small amounts of alcohol. Ask your doctor or pharmacist about the safe use of this product if you have diabetes.

This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages.

Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially drowsiness.

This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.

If this medication is used during the last 3 months of pregnancy, infrequently your newborn may develop symptoms including feeding or breathing difficulties, seizures, muscle stiffness, jitteriness

or constant crying. However, do not stop taking this medication unless your doctor directs you to do so. Report any such symptoms to your doctor promptly.

Fluoxetine passes into breast milk and may have undesirable effects on a nursing infant. Therefore, breast-feeding while taking this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Certain medications taken with this product could result in serious, possibly fatal, drug interactions. Avoid taking MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, selegiline, tranylcypromine) with or within 2 weeks of starting fluoxetine or at least 5 weeks after stopping it.

Also avoid taking thioridazine with this medication or within 5 weeks after stopping treatment. Consult your doctor for more information.

This drug should not be used with the following medications because very serious (possibly fatal) interactions may occur: astemizole, terfenadine.

If you are currently using any of these medications, tell your doctor or pharmacist before starting fluoxetine.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: certain anti-anxiety drugs (e.g., alprazolam, diazepam, buspirone), other SSRI anti-depressants (e.g., citalopram, sertraline), tricyclic anti-depressants (e.g., amitriptyline, imipramine), other anti-depressant drugs (e.g., nefazodone, trazodone, venlafaxine), anti-seizure drugs (e.g., carbamazepine, phenytoin), atomoxetine, dextromethorphan, certain herbal products (e.g., ayahuasca, St John's wort), isoniazid, lithium, meperidine, drugs to treat migraines (e.g., ergotamine, "triptans" such as sumatriptan), pentazocine, psychiatric medications (e.g., aripiprazole, clozapine, haloperidol, pimozide, risperidone), tramadol, tryptophan, weight loss drugs (e.g., sibutramine, phentermine), drugs removed from your system by certain liver enzymes (CYP 2D6 substrates such as amphetamines, flecainide, metoprolol, propafenone, vinblastine), other drugs which can cause bleeding/bruising (e.g., thrombolytic drugs such as TPA, anticoagulants such as heparin or warfarin, antiplatelet drugs including NSAIDs such as ibuprofen).

Low-dose aspirin (usually 81-325 mg per day) for heart attack or stroke prevention should be continued unless your doctor instructs you otherwise. Aspirin is similar to NSAID drugs, and can increase the risk of bleeding in combination with this medication (see above). Discuss the risks and benefits with your doctor.

Tell your doctor or pharmacist if you also take drugs that cause drowsiness such as: certain antihistamines (e.g., diphenhydramine), medicine for sleep (e.g., sedatives), muscle relaxants, narcotic pain relievers (e.g., codeine), tranquilizers.

Check all prescription and nonprescription medicine labels carefully (e.g., cough-and-cold products, pain relievers/fever reducers) for ingredients which may increase the risk of side effects. Ask your pharmacist about the safe use of those products.

Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE:

If overdose is suspected, contact your local poison control center or emergency room

immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: persistent nausea/vomiting, fast/abnormal heartbeats, severe drowsiness, seizures, loss of consciousness, severe mental/mood changes.

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature between 59-86 degrees F (15-30 degrees C), away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

MEDICAL ALERT: Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).