

17.11 Use in Specific Populations

Pregnancy — Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. Fluoxetine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus [see [Use in Specific Populations \(8.1\)](#)].

Nursing Mothers — Patients should be advised to notify their physician if they intend to breastfeed an infant during therapy. Because fluoxetine is excreted in human milk, nursing while taking SARAFEM is not recommended [see [Use in Specific Populations \(8.3\)](#)].

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Content Updated: October 2014

Medication Guide

SARAFEM[®] (SAIR-a-fem)
(fluoxetine hydrochloride)
Tablets

Read the Medication Guide that comes with SARAFEM 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 with your healthcare provider if there is something you do not understand or you want to learn more about.

SARAFEM is in a class of drugs called selective serotonin reuptake inhibitors (SSRIs), which are often used for the treatment of depression and anxiety disorders. Although SARAFEM is not a treatment for depression, it contains fluoxetine hydrochloride, the same active ingredient in some antidepressants.

What is the most important information I should know about SARAFEM?

SARAFEM and other antidepressant medicines may cause serious side effects including:

1. Suicidal thoughts or actions:

- **SARAFEM 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 SARAFEM 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 if 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 if an emergency. SARAFEM 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
- dizziness
- flushing
- tremor
- seizures

3. 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

4. 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

5. Seizures or convulsions

6. Changes in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

7. Abnormal bleeding: SARAFEM 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 (NSAID's, like ibuprofen or naproxen), or aspirin.

8. 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.

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 SARAFEM without first talking to your healthcare provider. Stopping SARAFEM too quickly 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 is SARAFEM?

SARAFEM is a prescription medicine used to treat premenstrual dysphoric disorder (PMDD).

It is not known if SARAFEM is safe and effective in children.

Talk with your healthcare provider if you do not think that your condition is getting better with SARAFEM treatment.

Who should not take SARAFEM?

Do not take SARAFEM if you:

- 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 5 weeks of stopping SARAFEM unless directed to do so by your healthcare provider.
 - Do not start SARAFEM if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.

Women who take SARAFEM 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). Do not take Mellaril® within 5 weeks of stopping SARAFEM because this can cause serious**

heart rhythm problems or sudden death.

- **take the antipsychotic medicine pimozide (Orap[®]) because this can cause serious heart problems.**

What should I tell my healthcare provider before taking SARAFEM?

Ask if you are not sure.

Before starting SARAFEM, tell your healthcare provider if you:

- Are taking certain drugs or treatments such as:
 - Triptans used to treat migraine headache
 - Medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, buspirone, SSRIs, SNRIs, MAOIs or antipsychotics
 - Tramadol and fentanyl
 - Over-the-counter supplements such as tryptophan or St. John's Wort
 - Electroconvulsive therapy (ECT)
- 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 SARAFEM will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Some SARAFEM may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking SARAFEM.

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

If you take SARAFEM, you should not take any other medicines that contain fluoxetine hydrochloride:

- Symbiyax®
- Prozac®
- Prozac® Weekly™

How should I take SARAFEM?

- Take SARAFEM exactly as prescribed. Your healthcare provider may need to change the dose of SARAFEM until it is the right dose for you.
- Talk to your healthcare provider if your symptoms do not get better.
- SARAFEM may be taken with or without food.
- If you take too much SARAFEM, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking SARAFEM?

SARAFEM 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 SARAFEM affects you. Do not drink alcohol while using SARAFEM.

What are the possible side effects of SARAFEM?

SARAFEM may cause serious side effects, including:

- See “What is the most important information I should know about SARAFEM?”
- **Problems with blood sugar control.** Women who have diabetes and take SARAFEM may have problems with low blood sugar while taking SARAFEM. High blood sugar can happen when SARAFEM is stopped. Your healthcare provider may need to change the dose of your diabetes medicines when you start or stop taking SARAFEM.
- **Feeling anxious or trouble sleeping**

The most common side effects of SARAFEM include:

- headache
- weakness (asthenia)
- pain
- accidental injury
- infection
- flu symptoms
- nausea
- diarrhea

- trouble sleeping (insomnia)
- dizziness
- feeling anxious or nervous
- thinking differently
- sexual problems
- runny or stuffy nose (rhinitis)
- sore throat (pharyngitis)

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 SARAFEM. 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 SARAFEM?

- Store SARAFEM at room temperature between 68° F and 77° F (20° C to 25° C).

Keep SARAFEM and all medicines out of the reach of children.

General information about SARAFEM

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SARAFEM for a condition for which it was not prescribed. Do not give SARAFEM to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about SARAFEM. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about SARAFEM that is written for healthcare professionals. For more information about SARAFEM call 1-800-521-8813.

What are the ingredients in SARAFEM?

Active ingredient: fluoxetine hydrochloride

Inactive ingredients: microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, FD&C Yellow No. 6 aluminum lake (10 mg and 20 mg tablets) and D&C Yellow No. 10 aluminum lake (10 mg and 20 mg tablets)

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

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