

Important Information about Sarafem[®] (fluoxetine hydrochloride)

What is SARAFEM?

- SARAFEM is a medicine approved by the FDA to treat the symptoms of Premenstrual Dysphoric Disorder (PMDD) in adult women who have menstrual periods or cycles.
- SARAFEM is available by prescription only.

What is the active ingredient in SARAFEM?

- SARAFEM contains fluoxetine hydrochloride, the same ingredient as found in Prozac[®], Prozac[®]Weekly[™], and generic versions of Prozac.

Who should not take SARAFEM?

You should not take SARAFEM if you:

- are allergic to SARAFEM, or any of its components, or have had a bad reaction to Prozac, Prozac Weekly or generic fluoxetine previously.
- are taking a type of antidepressant medicine known as a monoamine oxidase inhibitor (MAOI), such as Nardil[®] (phenelzine sulfate) or Parnate[®] (tranylcypromine sulfate). Using an MAOI together with many prescription medicines, including SARAFEM, can cause serious or even life-threatening reactions. You must wait at least 14 days after you have stopped taking an MAOI before you can take SARAFEM. Also, you need to wait at least 5 weeks after you stop taking SARAFEM before you take an MAOI.
- are taking a type of antipsychotic medicine known as Mellaril[®] (thioridazine). Also, you need to wait at least 5 weeks after you stop taking SARAFEM before you take Mellaril.
- are taking a type of antipsychotic medicine known as Orap[®] (pimozide).

Although SARAFEM is not a treatment for depression, it contains fluoxetine hydrochloride, the same active ingredient in some antidepressants.

In clinical studies, antidepressants increased the risk of suicidal thinking and behavior in children, adolescents, and young adults with depression and other psychiatric disorders. Anyone considering the use of SARAFEM or any other antidepressant must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidal thinking or behavior with antidepressants in adults older than 24; there was a reduction in risk with antidepressants in adults 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely. Families and caregivers should discuss with the healthcare provider right away any observations of worsening depression symptoms, suicidal thinking and behavior, or unusual changes in behavior. SARAFEM is not approved for use in patients under age 18.

What should I talk to my doctor or pharmacist about?

- Patients taking antidepressants and their families or caregivers should watch for worsening depression symptoms, unusual changes in behavior and thoughts of suicide, as well as for anxiety, agitation, panic attacks, difficulty sleeping, irritability, hostility, aggressiveness, impulsivity, restlessness, or extreme hyperactivity. Call the doctor if you have thoughts of suicide or if any of these symptoms are severe or occur suddenly. Be especially observant within the first few months of treatment or whenever there is a change in dose. You should not stop taking SARAFEM abruptly. Talk to your doctor

before you stop taking SARAFEM. If you need more information, a Medication Guide is available from your doctor or pharmacist.

- If you get a rash or hives while taking SARAFEM, call your doctor right away because this can be a sign of a serious medical condition.
- Be sure to tell your doctor if you are taking Prozac, Prozac Weekly or generic versions of Prozac since these contain fluoxetine hydrochloride, the same active ingredient found in SARAFEM.
- Tell your doctor about all the nonprescription and prescription medicines you are taking, including those for migraine, to avoid a potentially life-threatening condition. Also, tell your doctor if you are taking or plan to take any vitamins, herbal supplements or alcohol.
- Be sure to tell your doctor if you are taking SARAFEM and are taking or plan to take non-steroidal anti-inflammatory drugs or aspirin since combined use of these drug products have been associated with an increased risk of bleeding.
- You should tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding while you are taking SARAFEM. Some newborns exposed to fluoxetine late in the mother's third trimester have needed special care.
- Tell your doctor if you have diabetes. The dose of diabetes medicine may change when you start or stop taking SARAFEM.
- Tell your doctor about any other medical conditions you may have especially liver disease or seizures.
- Tell your doctor if you have ever been told you had Bipolar Disorder (“Manic Depression”) or have had a “manic” or “psychotic” episode.

What are possible side effects of SARAFEM?

- Some women may experience side effects such as stuffy/runny nose, headache, nausea, weakness, flu syndrome, sore throat, difficulty sleeping, decreased sex drive, pain, accidental injury, nervousness, dizziness, infection, diarrhea and difficulty concentrating. Most of these tend to go away within a few weeks of starting treatment and, in most cases, aren't serious enough to cause people to stop taking SARAFEM.
- SARAFEM can cause changes in sexual desire or satisfaction.
- Do not drive a car or operate dangerous machinery until you know what effects SARAFEM may have on you.
- Contact your doctor or healthcare professional if you get a rash or hives, or other side effects that concern you while taking SARAFEM.

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