

1. **What is WELLSYL (wells-ee) (flibanserin) Tablets?**

FLIBANSERIN is a prescription medicine used to treat hypoactive (low) sexual desire disorder (HSDD) in women <65 years of age who have not had problems with low sexual desire in the past, and who have low sexual desire no matter the type of sexual activity, the situation, or the sexual partner. Women with HSDD have low sexual desire that is troubling to them. Their low sexual desire is not due to:

- a medical or mental health problem
- problems in the relationship
- medicine or other drug use.

FLIBANSERIN is not for use in men or in children, or to improve sexual performance.

2. **IMPORTANT SAFETY INFORMATION**

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

Your risk of severe low blood pressure and fainting (loss of consciousness) is increased:

- if you drink alcohol close to the time you take your FLIBANSERIN dose,
- if you take FLIBANSERIN with certain medicines, or
- if you have liver problems and you take FLIBANSERIN.

To lower your risk of low blood pressure and fainting (loss of consciousness):

- Do not drink alcohol close to the time you take your FLIBANSERIN dose
 - Wait at least 2 hours after drinking 1 or 2 standard alcoholic drinks before taking FLIBANSERIN at bedtime.
 - Skip your FLIBANSERIN dose if you drink 3 or more standard alcoholic drinks that evening.
- After taking FLIBANSERIN at bedtime do not drink alcohol until the following day.

Tell your doctor about other medicines you take. Do not take or start taking any prescription or over-the-counter medicines, or herbal supplements without first talking to your doctor.

Do not take FLIBANSERIN if you have liver problems.

If you take Flibanserin and feel lightheaded or dizzy, lie down right away. Call for help if the symptoms do not go away.

3. **Who should not take FLIBANSERIN?**

Do not take FLIBANSERIN if you:

- take certain medicines. Taking FLIBANSERIN with certain other medicines can increase the amount of FLIBANSERIN in your blood and cause severe low blood pressure, fainting (loss of consciousness), and sleepiness.
- Do not take FLIBANSERIN if you are taking any of the following: certain medicines to treat HIV-1 infection, fungal infections, antibiotics, Hepatitis C infection, high blood pressure, chest pain (angina), or other heart problems, nefazodone used to treat depression.
- have liver problems

4. **What should I tell my doctor before taking FLIBANSERIN?**

Before you take FLIBANSERIN, tell your doctor about all of your medical conditions, including if you:

- drink alcohol, use drugs, or have a history of alcohol or drug abuse
- have ever had depression or other mental health problems
- have low blood pressure or a medical condition that can cause low blood pressure
- are pregnant or plan to become pregnant. It is not known if FLIBANSERIN will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if FLIBANSERIN passes into your breast milk. You and your doctor should decide if you will take FLIBANSERIN or breastfeed. You should not do both.

Tell your doctor if you have had an allergic reaction such as hives, itching, or trouble breathing during or after receiving a dose of FLIBANSERIN.

Tell your doctor about all of the medicines you take, FLIBANSERIN can affect the way other medicines work, and other medicines can affect the way FLIBANSERIN works, and can cause serious side effects.

5. **What should I avoid while taking FLIBANSERIN?**

- Do not drink alcohol close to the time you take your FLIBANSERIN dose.
- Do not drive, operate machinery, or do things that require clear thinking until at least 6 hours after you take FLIBANSERIN and until you know how FLIBANSERIN affects you.
- Do not drink grapefruit juice if you take FLIBANSERIN. Drinking grapefruit juice during your treatment with FLIBANSERIN increases your risk of severe low blood pressure and fainting (loss of consciousness).
- You should not take the herbal supplements St. John's Wort, ginkgo, or resveratrol or certain over-the-counter medicines such as cimetidine until you talk to your doctor. Taking with FLIBANSERIN may increase your risk of low blood pressure, fainting (loss of consciousness), and sleepiness.

6. **What are the possible side effects of FLIBANSERIN?**

FLIBANSERIN can cause serious side effects, including:

- **Sleepiness** is a common side effect of FLIBANSERIN and can be serious.
- **Low blood pressure and fainting (loss of consciousness)** can happen when you take FLIBANSERIN even if you do not drink alcohol or take other medicines or herbal supplements. Your risk of sleepiness, low blood pressure and fainting is increased if FLIBANSERIN is taken during waking hours, if you drink alcohol (risk of low blood pressure and fainting is increased within 2 hours of taking FLIBANSERIN), or take certain medicines or herbal supplements.

The most common side effects of FLIBANSERIN include:

- Dizziness
- Difficulty falling asleep or staying asleep
- Nausea
- Dry mouth
- Tiredness

These are not all of the possible side effects of FLIBANSERIN. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.