

MEDICATION GUIDE
Flibanserin
Capsules & tablets,
for oral use

Read this Medication Guide before you start taking Flibanserin and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor.

What is the most important information I should know about ?

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.



**Before Taking
Flibanserin**

Skip your Flibanserin dose if you drink 3 or more standard alcoholic drinks that evening.



**Skip
Flibanserin
Dose**

- **After taking Flibanserin at bedtime do not drink alcohol until the following day.**

Examples of 1 standard alcoholic drink include:

- one 12-ounce regular beer
- 5 ounces of wine
- 1.5 ounces of distilled spirits or shot

- **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. Your doctor will tell you if it is safe to take other medicines or herbal supplements while you are taking Flibanserin.
- **Do not take Flibanserin if you have liver problems.**

If you take Flibanserin and you feel lightheaded or dizzy, lie down right away. Get emergency medical help or ask someone to get emergency medical help for you if the symptoms do not go away or if you feel like you could faint (lose consciousness). If you faint (lose consciousness), tell your doctor as soon as you can.

What is Flibanserin?

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.

Flibanserin is not for use to improve sexual performance.

Flibanserin is not for use in children.

Who should not take Flibanserin? Do not take Flibanserin if you:

- take certain other 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 medicines:

- o certain medicines used to treat HIV-1 infection, such as:

- amprenavir
 - atazanavir (REYATAZ®)
 - fosamprenavir (LEXIVA)
 - ritonavir (NORVIR)
 - saquinavir (INVIRASE®)
 - nelfinavir (VIRACEPT®)
 - indinavir (CRIXIVAN®)
 - o certain medicines that you take by mouth used to treat fungal infections, such as:
 - fluconazole (DIFLUCAN®)
 - ketoconazole
 - itraconazole (ONMEL, SPORANOX®)
 - posaconazole (NOXAFIL®)
 - o certain antibiotics, including:
 - ciprofloxacin (CIPRO, CIPRO XR)
 - erythromycin (ERY-TAB®, ERYC®, PCE®)
 - telithromycin (KETEK®)
 - clarithromycin (BIAXIN®)
 - o certain medicines used to treat Hepatitis C infection, such as:
 - boceprevir (VICTRELIS®)
 - telaprevir
 - o certain medicines used to treat high blood pressure, chest pain (angina), or other heart problems, such as:
 - diltiazem (CARDIZEM®, CARDIZEM CD®, CARDIZEM LA®, CARTIA XT, DILT CD, DILTZAC, TAZTIA XT, Tiazac®)
 - verapamil (CALAN®, CALAN® SR, COVERA-HS®, Verelan®, Verelan PM)
 - conivaptan (Vaprisol®)
 - o nefazodone: a medicine used to treat depression
- Ask your doctor or pharmacist if you are not sure if you take any of the medicines listed above. These are examples of the medicines that you should not take if you are taking Flibanserin. Tell your doctor about all of the medicines you take before you start taking Flibanserin.
- Do not take Flibanserin if you have liver problems

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 about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Flibanserin can affect the way other medicines work, and other medicines can affect the way Flibanserin works, and can cause serious side effects.

Know the medicines and herbal supplements you take. Keep a list of them to show your doctor or pharmacist each time you get a new medicine.

How should I take Flibanserin

- Take Flibanserin exactly as your doctor tells you to take it.
- Take 1 Flibanserin capsule or tablet no more than one time a day at bedtime.
- Take Flibanserin only at bedtime. Taking Flibanserin at a time other than bedtime can increase your risk of low blood pressure, fainting (loss of consciousness), accidental injury, and sleepiness.
- **If you drink alcohol, see “What is the most important information I should know about Flibanserin?”**
- **If you miss a dose of Flibanserin, skip your missed dose. Take your next dose at bedtime the next day. Do not** take Flibanserin the next morning or double your next dose. If you take too much Flibanserin, call your doctor.
- Tell your doctor if your symptoms of HSDD have not improved after you have taken Flibanserin for 8 weeks.

What should I avoid while taking Flibanserin?

- **Do not drink alcohol close to the time you take your Flibanserin dose because this increases your risk of severe low blood pressure and fainting (loss of consciousness).**
- **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 Flibanserin with these herbal supplements and

over-the-counter medicine may increase your risk of low blood pressure, fainting (loss of consciousness), and sleepiness.

What are the possible side effects of Flibanserin? Flibanserin can cause serious side effects, including:

- See “**What is the most important information I should know about Flibanserin?**”
- **Sleepiness** is a common side effect of Flibanserin and can be serious. Taking Flibanserin can increase your risk of sleepiness if taken during waking hours, if you drink alcohol, or take certain medicines or herbal supplements.
- **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 low blood pressure and fainting (loss of consciousness) is increased if Flibanserin is taken during waking hours, if you drink alcohol within 2 hours of taking Flibanserin, or if you take certain medicines or herbal supplements.

The most common side effects of Flibanserin include:

- dizziness
- nausea
- tiredness
- difficulty falling asleep or staying asleep
- dry mouth

These are not all of the possible side effects of Flibanserin.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-332-1088.

How should I store Flibanserin?

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

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

General information about the safe and effective use of Flibanserin

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Flibanserin for a condition for which it was not prescribed. Do not give Flibanserin to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about Flibanserin that is written for health professionals.

NOTE: This sheet is a summary. It may not cover all possible information. Call your doctor for medical advice and/or about side effects. You may report effects to the FDA at 1-800-FDA-1088. A Wells Pharmacy Network pharmacist will be happy to answer any questions. For consultation, please call 1-800-622-4510.