MEDICATION GUIDE
ADDYI® (add-ee)
(flibanserin)Tablets

Read this Medication Guide before you start taking ADDYI® 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 ADDYI?
Your risk of SEVERE LOW BLOOD PRESSURE AND FAINTING (LOSS OF CONSCIOUSNESS) is increased if you take ADDYI and:

- **drink alcohol. Do not drink alcohol if you take ADDYI.**
- **take certain prescription medicines, over-the-counter medicines, or herbal supplements. Do not take or start taking any prescription medicines, over-the-counter medicines, or herbal supplements while taking ADDYI until you have talked with your doctor.** Your doctor will tell you if it is safe to take other medicines or herbal supplements while you are taking ADDYI.
- **have liver problems.** Do not take ADDYI if you have liver problems.

If you take ADDYI 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 faint (lose consciousness). If you faint (lose consciousness), tell your doctor as soon as you can.

ADDYI is only available through the ADDYI risk evaluation and mitigation strategy (REMS) Program because of the increased risk of severe low blood pressure and fainting (loss of consciousness) with alcohol use. You can only get ADDYI from pharmacies that are enrolled in the ADDYI REMS Program. For more information about the Program and a list of pharmacies that are enrolled in the ADDYI REMS Program, go to www.AddyiREMS.com or call 1-844-PINK-PILL (1-844-746-5745).

What is ADDYI?
ADDYI is a prescription medicine used to treat hypoactive (low) sexual desire disorder (HSDD) in women who have not gone through menopause, 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

ADDYI is not for use for the treatment of HSDD in women who have gone through menopause or in men.

ADDYI is not for use to improve sexual performance.

ADDYI is not for use in children.

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

- drink alcohol
- take certain other medicines. Taking ADDYI with certain other medicines can increase the amount of ADDYI in your blood and cause severe low blood pressure, fainting (loss of consciousness), and sleepiness.

  Do not take ADDYI if you are taking any of the following medicines:

  - certain medicines used to treat HIV-1 infection, such as:
    - amprenavir
    - ritonavir (NORVIR)
    - indinavir (CRIXIVAN)
    - atazanavir (REYATAZ)
    - saquinavir (INVIRASE)
    - fosamprenavir (LEXIVA)
    - nelfinavir (VIRACEPT)
  - certain medicines that you take by mouth used to treat fungal infections, such as:
    - fluconazole (DIFLUCAN)
    - itraconazole (ONMEL, SPORANOX)
    - ketoconazole
    - posaconazole (NOXAFIL)
  - certain antibiotics, including:
    - ciprofloxacin (CIPRO, CIPRO XR)
    - telithromycin (KETEK)
    - erythromycin (ERY-TAB, ERYC, PCE)
    - clarithromycin (BIAXIN)
  - certain medicines used to treat Hepatitis C infection, such as:
    - boceprevir (VICTRELIS)
    - telaprevir
  - 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)
  - 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 ADDYI. Tell your doctor about all of the medicines you take before you start taking ADDYI.
- have liver problems

What should I tell my doctor before taking ADDYI?
Before you take ADDYI, 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 ADDYI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ADDYI passes into your breast milk. You and your doctor should decide if you will take ADDYI 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. ADDYI can affect the way other medicines work, and other medicines can affect the way ADDYI 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 ADDYI?

- Take ADDYI exactly as your doctor tells you to take it.
- Take 1 ADDYI tablet one time a day at bedtime.
- Take ADDYI only at bedtime. Taking ADDYI at a time other than bedtime can increase your risk of low blood pressure, fainting (loss of consciousness), accidental injury, and sleepiness.
- If you miss a dose of ADDYI, skip your missed dose. Take your next dose at bedtime the next day. Do not take ADDYI the next morning or double your next dose. If you take too much ADDYI, call your doctor.
- Tell your doctor if your symptoms of HSDD have not improved after you have taken ADDYI for 8 weeks.

What should I avoid while taking ADDYI?

- Do not drive, operate machinery, or do things that require clear thinking until at least 6 hours after you take ADDYI and until you know how ADDYI affects you.
- Do not drink grapefruit juice if you take ADDYI. Drinking grapefruit juice during your treatment with ADDYI 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 ADDYI 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 ADDYI?
ADDYI can cause serious side effects, including:

- See "**What is the most important information I should know about ADDYI?**"
- **Sleepiness** is a common side effect of ADDYI and can be serious. Taking ADDYI 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 ADDYI 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 ADDYI is taken during waking hours, if you drink alcohol, or if you take certain medicines or herbal supplements.

The most common side effects of ADDYI include:

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

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

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 ADDYI?

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

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

General information about the safe and effective use of ADDYI
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ADDYI for a condition for which it was not prescribed. Do not give ADDYI 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 ADDYI that is written for health professionals.

What are the ingredients in ADDYI?

Active ingredient: flibanserin

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, hypromellose, croscarmellose sodium, magnesium stearate, talc, macrogol, and the coloring agents, titanium dioxide and iron oxide.

sprout pharmaceuticals

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For more information go to www.ADDYI.com or call 1-844-PINK-PILL (1-844-746-5745).

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

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