What if

THERE WAS A PILL TO IMPROVE A WOMAN'S SEX DRIVE? THERE IS. ADDYI.

ADDYI (flibanserin), is the only FDA-approved pill proven effective for Hypoactive Sexual Desire Disorder (HSDD) in certain premenopausal women.

Visit AddyiHCP.com

As seen in COSMOPOLITAN VOGUE GLAMOUR BUSINESS INSIDER Entrepreneur healthline

ADDYI (flibanserin) is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:

- A co-existing medical or psychiatric condition,
- Problems within the relationship, or
- The effects of a medication or other drug substance.

Acquired HSDD refers to HSDD that develops in a patient who previously had no problem with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation, or partner.

Limitations of Use:

- ADDYI is not indicated for the treatment of HSDD in postmenopausal women or in men.
- ADDYI is not indicated to enhance sexual performance.

IMPORTANT SAFETY INFORMATION

WARNING: HYPOTENSION AND SYNCOPE IN CERTAIN SETTINGS

See full prescribing information for complete boxed warning.

- Use of ADDYI and alcohol together close in time increases the risk of severe hypotension and syncope. Counsel patients to wait at least two hours after consuming one or two standard alcoholic drinks before taking ADDYI at bedtime or to skip their ADDYI dose if they have consumed three or more standard alcoholic drinks that evening.
- Severe hypotension and syncope can occur when ADDYI is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore, ADDYI use in these settings is contraindicated.

See additional Important Safety Information throughout, including Boxed Warning regarding hypotension and syncope in certain settings, and Full Prescribing Information and Medication Guide at addyi.com/pi.

ADDYI IS THE #1 PRESCRIBED TREATMENT FOR HSDD[1]

Addyi is the #1 prescribed treatment for women with HSDD who want to improve their sex drive. Women who have not gone through menopause, who have not had problems with low sexual desire in the past, and who have frustrating low sexual desire no matter the type of sexual activity, the situation, or the sexual partner, are candidates for Addyi.

THE NEUROCHEMISTRY OF *Desire*

In women with hypoactive sexual desire disorder, deactivation of their medial orbitofrontal cortex can produce a decrease in PAG-POSC activation, causing absence of vaginal vasocongestion and lubrication and decreased sexual behavior in general.[2]

WITH HSDD* **WITHOUT HSDD***

In animal and *in vitro* studies, flibanserin has shown 5-HT1a agonist and 5-HT2a antagonist activity.[3]

Addyi is believed to increase dopamine and norepinephrine, and transiently decrease serotonin, restoring an appropriate balance of excitatory and inhibitory activity of brain reward centers to the prefrontal cortex.[3†]

*Rendering of brain PET scans; study in 24 women (age 18-47) who watched erotic movies for 2 minutes while lying with their head in a PET scanner.

†The exact mechanism of action of Addyi is unknown.

IMPORTANT SAFETY INFORMATION (Continued)

Contraindications

- Moderate or strong cytochrome P450 3A4 (CYP3A4) inhibitors
- Hepatic impairment
- Known hypersensitivity to ADDYI or any of its components. Reactions, including anaphylaxis, reactions consistent with angioedema, pruritus, and urticaria have been reported.

Warnings and Precautions

- Hypotension and Syncope Due to an Interaction with Alcohol: Taking ADDYI within two hours after consuming alcohol increases the risk of severe hypotension and syncope. To reduce this risk, counsel patients to wait at least two hours after drinking one or two standard alcoholic drinks before taking ADDYI at bedtime. Patients who drink three or more standard alcoholic drinks should skip their ADDYI dose that evening. After taking ADDYI at bedtime, advise patients to not use alcohol until the following day.

"It's not just that I want to look good, I want to FEEL good. Feel sexy! When my sex drive dimmed, I wanted to turn it on again."

– Jackie, 47

THE ADDYI Woman

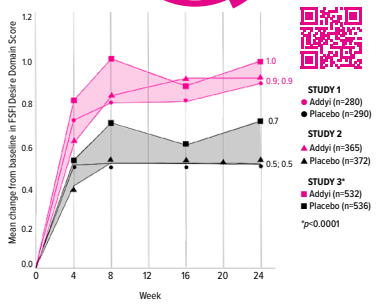
Meet the typical Addyi patient: She's navigating a silent struggle. Her sexual desire isn't what it used to be, leaving her feeling lost, frustrated and disconnected from the person she wants to be most connected to. With Addyi she finds more than a treatment for her desire; she discovers a pathway to feeling like herself again.

CLINICALLY PROVEN

ADDYI IS THE ONLY FDA APPROVED TREATMENT THAT DEMONSTRATED EFFECTIVENESS ACROSS ALL 3 CLINICAL TRIAL ENDPOINTS.

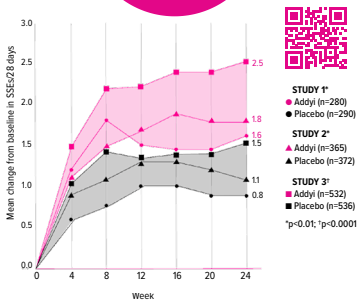
INCREASE HER SEXUAL DESIRE[4-7]

+50%
change from baseline in FSFI Desire Domain Score vs Placebo[7**]



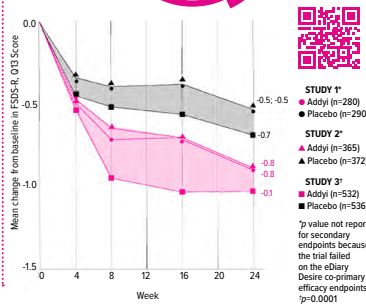
INCREASE HER SATISFYING SEXUAL EVENTS[4-7]

+75%
change from baseline in SSEs/28 Days vs Placebo[7**]



DECREASE HER DISTRESS[4-7]

-50%
change from baseline in FSDS-R, Q13 Score vs Placebo[7**]



**Pooled analysis of studies 1, 2, and 3

IMPORTANT SAFETY INFORMATION (Continued)

- Hypotension and Syncope with CYP3A4 Inhibitors: Moderate or strong CYP3A4 inhibitors significantly increase ADDYI concentrations, which can lead to hypotension and syncope. Concomitant use of ADDYI with a moderate or strong CYP3A4 inhibitor is contraindicated. Concomitant use of multiple weak CYP3A4 inhibitors that may include herbal supplements (e.g., ginkgo, resveratrol) or non-prescription drugs (e.g., cimetidine) could also lead to clinically relevant increases in flibanserin concentrations that may increase the risk of hypotension and syncope.
- Central Nervous System (CNS) Depression (e.g., Somnolence, Sedation): Can occur with ADDYI alone and is exacerbated by other CNS depressants including alcohol, and in settings where flibanserin concentrations are increased such as CYP3A4 inhibitors. The risk of CNS depression is also increased if ADDYI is taken during waking hours. Patients should avoid activities requiring full alertness (e.g., operating machinery or driving) until at least six hours after each dose and until they know how ADDYI affects them.

THE STRESS OF HSDD GOES BEYOND THE BEDROOM

1 OUT OF 10[8]
WOMEN STRUGGLE WITH FRUSTRATING LOW LIBIDO

1 OUT OF 3[9]
ARGUE WITH THEIR PARTNER ABOUT THEIR LACK OF DESIRE FOR SEX

2 OUT OF 3[9]
FEEL LESS CONNECTED TO THEIR PARTNER

1 OUT OF 3[9]
WORRY THEIR PARTNER WILL CHEAT

SETTING *Expectations*

Women may experience results in as little as **4 weeks** but set her expectations to give Addyi **2 months** to experience continuously improving results.[†] Let her know she may begin to notice sexual fantasies returning, become more receptive to her partner; and even initiate sex herself.

[†] Addyi should be discontinued if there is no improvement after 8 weeks. Individual results may vary.

CONTRAINDICATIONS

1. Moderate or strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g. ketoconazole, ritonavir)
2. Hepatic impairment
3. Known hypersensitivity to ADDYI or its components

COMMON ADVERSE REACTIONS IN 4 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIALS IN PREMENOPAUSAL WOMEN WITH HSDD. ADVERSE REACTIONS LED TO LESS THAN 2% DISCONTINUATION.

ADVERSE REACTIONS LEADING TO DISCONTINUATION*

	PLACEBO (n=1556)	ADDYI (n=1543)
Dizziness	0.1%	1.7%
Nausea	0.1%	1.2%
Insomnia	0.2%	1.1%
Somnolence	0.3%	1.1%
Anxiety	0.3%	1.0%

* Adverse reactions leading to discontinuation in ≥ 1% of patients receiving 100 mg Addyi at bedtime and at a higher incidence than placebo-treated patients. The discontinuation rate due to adverse reactions was 13% among patients treated with 100mg Addyi at bedtime and 6% among patients treated with placebo.

MOST COMMON ADVERSE REACTIONS**

	PLACEBO (n=1556)	ADDYI (n=1543)
Dizziness	2.2%	11.4%
Somnolence	2.9%	11.2%
Nausea	3.9%	10.4%
Fatigue	5.5%	9.2%
Insomnia	2.8%	4.9%
Dry Mouth	1.0%	2.4%

**Adverse reactions reported in ≥ 2% of patients receiving 100 mg Addyi at bedtime and at a higher incidence than placebo-treated patients. The majority of these adverse reactions began within the first 14 days of treatment

IMPORTANT SAFETY INFORMATION (Continued)

- Hypotension and Syncope with ADDYI Alone: The use of ADDYI – without other concomitant medications known to cause hypotension or syncope – can cause hypotension and syncope. The risk of hypotension and syncope is increased if ADDYI is taken during waking hours or if higher than the recommend dose is taken. Consider the benefits of ADDYI and the risks of hypotension and syncope in patients with pre-existing conditions that predispose to hypotension. Patients with pre-syncope should immediately lie supine and promptly seek medical help if symptoms do not resolve. Prompt medical attention should also be obtained for patients who experience syncope.
- Syncope and Hypotension in Patients with Hepatic Impairment: Any degree of hepatic impairment significantly increases flibanserin concentrations, which can lead to hypotension and syncope. ADDYI is contraindicated in patients with hepatic impairment.
- Hypersensitivity Reactions: Reactions including anaphylaxis, reactions consistent with angioedema, pruritus, and urticaria have been reported with ADDYI. Immediately discontinue ADDYI and initiate appropriate treatment if hypersensitivity reaction occurs.

70% OF PATIENTS WANT YOU TO START THE CONVO ABOUT SEXUAL HEALTH[10]

"After a few weeks on Addyi I felt like my old self again... I was even having fantasies! I could not wait until date night!"

– Erica S, 34

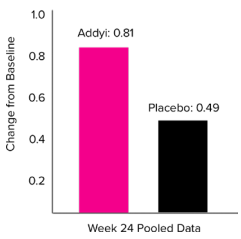
HSDD is a common yet often unspoken issue that many women experience, and it's time to bring this important conversation into the light. Let's start the conversation and empower women to feel confident and fulfilled in every aspect of their lives.

ADDITIONAL *Data*

LEARN MORE

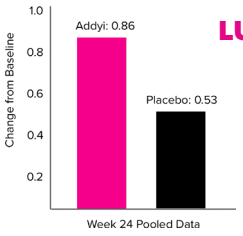
POST HOC ANALYSIS OF FEMALE SEXUAL FUNCTION INDEX (FSFI)‡

Post hoc analyses of FSFI total and individual domain data were pooled from 3 pivotal, multicenter, randomized, placebo-controlled, double-blind trials in premenopausal women with HSDD who received flibanserin (n=1165) or placebo (n=1203).[11] **Addyi has not been studied for the treatment of any female sexual dysfunction other than acquired, generalized HSDD.**



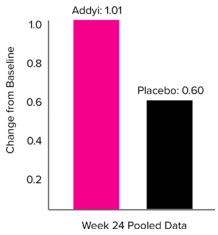
ORGASM

+65% change from baseline in FSFI-Orgasm score vs Placebo



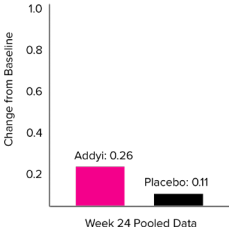
LUBRICATION

+62% change from baseline in FSFI-Lubrication score vs Placebo



AROUSAL

+68% change from baseline in FSFI-Arousal score vs Placebo



PAIN

-136% change from baseline in FSFI-Pain score vs Placebo

‡Post hoc analysis sponsored by Sprout.

IMPORTANT SAFETY INFORMATION (Continued)

Drug Interactions

- Alcohol: coadministration of ADDYI with alcohol increased the risk of hypotension, syncope, and CNS depression compared to the use of ADDYI alone or alcohol alone. Patients should wait at least two hours after consuming one or two standard alcoholic drinks before taking ADDYI at bedtime or to skip their ADDYI dose if they have consumed three or more alcoholic drinks that evening.
- CNS Depressants: (i.e., diphenhydramine, opioids, hypnotics, benzodiazepines, etc.) Concomitant use with ADDYI may increase the risk of CNS depression compared to use of ADDYI alone.
- Moderate or Strong CYP3A4 Inhibitors: ADDYI is contraindicated in women taking moderate (e.g., fluconazole, etc.) or strong (e.g., ketoconazole, etc.) CYP3A4 inhibitors
- Oral Contraceptives and Other Weak CYP3A4 Inhibitors: In combination with ADDYI may increase the risk of adverse reactions

LEARN MORE

Scan the QR code to learn more about Addyi's additional data.

- CLINICAL TRIAL SAFETY PROFILE
- EFFECT ON WEIGHT
- COADMINISTRATION WITH SSRI/SNRI

WHAT PRESCRIBERS ARE SAYING ABOUT *Addyi*

"Addyi has impacted the way we approach women's sexual health. Seeing my patients feel like themselves again has been incredibly rewarding."

– Mona Gupta, DO

"Addyi has been an invaluable addition to my toolbox, becoming a crucial component in the comprehensive care of my female patients experiencing stress due to low libido."

– Omotola T'Sarumi, MD

REFERENCES **1.** IQVIA Monthly Total Prescriptions Volume Data Comparing Addyi vs Vyleesi in the US. September 2022 – August 2023 **2.** Holstege G. Sex Med Rev. 2016;4(4):303-328. **3.** Stahl SM, et al. J Sex Med. 2011;8:15-27 **4.** Derogatis LR et al. J Sex Med. 2012;9(4):1074-1085. **5.** Thorp J, et al. J Sex Med. 2012;9(3):793-804. **6.** Katz M, et al. J Sex Med. 2013;10(7):1807-1815. **7.** Simon JA, et al. J Womens Health. 2019;28(6):769-777 **8.** Shifren JL, et al. Obstet Gynecol. 2008 Nov;112(5):970-978. **9.** Kingsberg SA. J Women's Health. 2014;23(10):817-23 **10.** Ryan KL, et al. PRiMER. 2018;2:23 **11.** Simon JA, et al. Sex Med. 2022 Dec;10(6):100570.

IMPORTANT SAFETY INFORMATION (Continued)

- Strong CYP2C19 Inhibitors: (i.e., proton pump inhibitors, SSRI's, benzodiazepines, antifungals, etc.) Increase flibanserin exposure which may increase risk of hypotension, syncope, and CNS depression
- CYP3A4 Inducers: (i.e., carbamazepine, phenobarbital, etc.) Concomitant use substantially decreases flibanserin exposure compared to the use of ADDYI alone and is not recommended.
- Digoxin or other P-glycoprotein (P-gp) substrates: Increases digoxin concentration, which may lead to digoxin toxicity. Increase monitoring of drugs transported by P-gp that have a narrow therapeutic index.

Most Common Adverse Reactions

- Most common adverse reactions (ADDYI incidence ≥2% and higher than placebo) are dizziness, somnolence, nausea, fatigue, insomnia, and dry mouth.

See additional Important Safety Information throughout, including Boxed Warning regarding hypotension and syncope in certain settings, and Full Prescribing Information and Medication Guide at addyi.com/pi. US--2100014.05

VISIT ADDYIHCP.COM TO LEARN MORE