

# Top 10 Things To Know About

# Addyi

Addyi is the first FDA approved drug to treat hypoactive sexual desire disorder (HSDD) in premenopausal women. Whether you're considering speaking with your clinician about Addyi or just interested in learning more about this new drug, it is important to know the facts.

## Addyi has only been tested in a small subset of women.

The participants who enrolled in the initial clinical trials for Addyi were premenopausal, heterosexual, and generally very healthy women. The overwhelming majority of these women identified as White (>85%), non-Hispanic (>86%), and non-smokers (>85%). Given the extensive list of exclusion criteria for the trials, the extent to which the trials' results can be generalized to the public is unknown.

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WHITE  
NON-SMOKER  
HETEROSEXUAL  
100%

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## Addyi may cause sudden prolonged unconsciousness.

Addyi causes central nervous system depression. During clinical trials, women who used Addyi were more likely to experience dangerously low blood pressure, dizziness, and even loss of consciousness than women taking placebo. These studies also revealed a higher incidence of accidental injury in women who used Addyi.

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## Alcohol should be avoided when taking Addyi.

Women may experience fatigue, low blood pressure, and fainting when using Addyi, all conditions which may be exacerbated when drinking alcohol. Women who are moderate drinkers (compared to heavy drinkers) may experience these effects more dramatically. The FDA asked Sprout (the company that owned Addyi) to conduct a safety study assessing these risks, but only two of the 25 participants in the alcohol safety study were women. Because the risks of using alcohol with Addyi are still unknown, the FDA is counting on women to abstain from alcohol permanently despite there being no known strategy to ensure people are able to do this in the long term.

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## Hormonal contraceptives may interfere with Addyi.

Some adverse events, including sleepiness (somnolence), dizziness and fatigue, were reported more often in women who used hormonal contraceptives. Hormonal contraceptives are known to affect a certain enzyme (CYP3A4) which may increase Addyi exposure by 40%. Young women, many of whom often use hormonal contraceptives, may face additional and unnecessary risk when using this drug.

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## Addyi may interfere with a lot of other drugs too.

Many other commonly used medications are also CYP3A4 inhibitors and may significantly increase Addyi exposure. This could lead to poor tolerability of Addyi, as well as increases in low blood pressure and fainting for women using Addyi. These medications include antiepileptic drugs, benzodiazepines, antidepressants, antipsychotics, mood stabilizers, narcotics, vaginal yeast infection medications, and even St. John's wort, all of which were excluded from Addyi's phase 3 studies.

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## Addyi is not “Viagra for women.”

Though Addyi has been dubbed the “female Viagra” in some media reports, the two drugs are very different. Viagra helps men who already want to have sex but are not able to physiologically. Addyi changes brain chemistry in women to help them want to want to have sex. Viagra is taken on an as needed basis to help increase blood flow to the penis. Addyi must be taken every day to be even minimally effective, and the effects go away as soon as you stop.

## Addyi was rejected by the Food and Drug Administration twice before.

Addyi was rejected by the FDA both in 2010 and 2013 because it simply did not work consistently better than placebo. Also, the drug’s sponsor was unable to prove Addyi’s minimal benefits outweighed its serious safety concerns.

7



10-12% RESPOND

8

## Addyi barely works, if at all.

After adjusting for placebo, only about 10-12% of women in clinical trials benefited even minimally from taking Addyi. For this small subset of women, the minimal benefits of taking Addyi seemed to be felt by about 8 weeks. This means women who want to try Addyi shouldn’t keep taking the drug beyond 8 weeks, if they do not feel like it is helping them.

## Addyi does not improve the ability to orgasm or the quality of sex.

Addyi works by changing brain chemistry to affect desire for sex, or libido, in premenopausal women. Addyi does not make it easier for women to achieve orgasm, nor does it make sex more enjoyable for either partner.

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## Women need more information about Addyi.

Unfortunately, there are still too many unresolved questions about the seriousness, severity, duration, and frequency of Addyi’s side effects. With good information, women can make the health care decision that is right for them. In this case, women have to decide whether or not to use Addyi without all the information they deserve.

## Help women learn more about Addyi by reporting problems:



If you experience a problem, side effect, or other adverse reaction after taking Addyi, consider reporting it at MedWatch, the FDA’s reporting system for drugs and medical device adverse events. Learn more at [fda.gov/safety/MedWatch](http://fda.gov/safety/MedWatch).