

## Flibanserin (Addyi) for Hypoactive Sexual Desire Disorder in Premenopausal Women

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STEPS new drug reviews cover Safety, Tolerability, Effectiveness, Price, and Simplicity. Each independent review is provided by authors who have no financial association with the drug manufacturer.

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Flibanserin (Addyi) is labeled for the treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women. It is a nonhormonal medication that affects serotonin receptors to increase libido.<sup>1</sup>

Drug	Dosage	Dose form	Cost*
Flibanserin (Addyi)	100 mg per day at bedtime	100-mg tablet	\$830

\*—Estimated retail price of one month's treatment based on information obtained at <http://www.goodrx.com> (accessed April 1, 2016).

### SAFETY

The main risks of flibanserin are hypotension (2%) and syncope (0.4%), which are more likely to occur in patients who have also ingested alcohol. For this reason, women should not drink alcohol when taking flibanserin; about one in six persons taking this combination will experience clinically significant hypotension and syncope.<sup>1</sup> Flibanserin should not be taken by women with hepatic impairment or women who are also taking moderate or strong cytochrome P450 3A4 inhibitors such as azole antifungals or protease inhibitors, which may increase serum levels.<sup>2</sup> Flibanserin should be taken at night because adverse effects are more prominent when it is taken in the morning. Pregnancy and breastfeeding should be avoided while taking flibanserin, because its effects on humans are not known.<sup>2</sup>

### TOLERABILITY

Dizziness (11.4%), somnolence (11.2%), nausea (10.4%), fatigue (9.2%), insomnia (4.9%), and dry mouth (2.4%) are reported with flibanserin but are less common when it is taken at bedtime. About one in eight patients will discontinue treatment because of adverse effects.<sup>1</sup>

### EFFECTIVENESS

Flibanserin has been evaluated in three randomized, double-blind, placebo-controlled studies of 2,375 premenopausal women with acquired, generalized HSDD, defined as low sexual desire causing marked distress or interpersonal difficulties.<sup>2</sup> Women in monogamous, heterosexual relationships with no known cause of HSDD reported an average increase of 1.6 to 2.5 additional satisfying sexual events per month with treatment, from a baseline of 2.5 to 3.0 per month. In comparison, women in the placebo group had an increase of 0.8 to 1.5 additional events per month. However, women taking flibanserin typically did not notice an increase in the intensity or frequency of sexual desire. In two of the three studies, distress associated with low sexual desire was not significantly improved with treatment compared with placebo.<sup>1</sup> The effects of flibanserin on quality of life or patient or partner satisfaction have not been studied. Flibanserin has not been studied in nonheterosexual women or in women who are not in stable relationships.

### PRICE

A one-month supply of flibanserin (100 mg per day) costs approximately \$830. ▶

**SIMPLICITY**

Flibanserin is taken once daily at night to lessen the likelihood of adverse effects. If not effective after eight weeks of treatment, the medication should be discontinued. Certification is required of physicians before prescribing, and prescriptions can only be dispensed by pharmacists who have completed this training as well.<sup>3</sup>

**Bottom Line**

Although flibanserin results in a modest improvement in the number of satisfying sexual events (approximately one more per month vs. placebo), it does not improve other measures, is considerably expensive, and has significant adverse effects. In addition, its approval process and the role of its manufacturer in that process have sparked controversy.<sup>4</sup> Unless further studies demonstrate better safety and effectiveness, flibanserin is best reserved for a

few select patients after more conservative options have been tried.

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