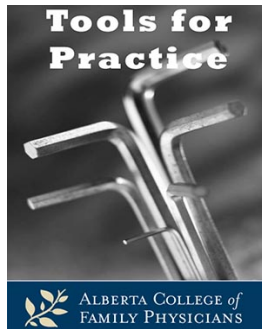


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## Flibanserin: Feeling frisky or falling over?

**Clinical Question: Does flibanserin improve sexual desire and the number of satisfying sexual episodes for women?**

**Bottom-line: Flibanserin results in ~7% improvement in desire and 0.4-1 additional “satisfying” sexual event per month. However, it is also associated with adverse events like dizziness or somnolence for one in 10-15 women. Concerns regarding hypotension, syncope, and interactions with commonly used drugs (particularly alcohol) are worrisome and require further research.**

### Evidence:

- Four double-blind randomized controlled trials of 1,581,<sup>1</sup> 880,<sup>2</sup> and 1,087<sup>3</sup> premenopausal women and 949<sup>4</sup> postmenopausal women with Hypoactive Sexual Desire Disorder. Flibanserin (versus placebo) demonstrated:
  - Statistically significant increase in “satisfying” sexual events: 0.4-1/28 days.<sup>3,4</sup>
  - No increase daily sexual desire.<sup>1,2</sup>
  - Increase in Female Sexual Function Index-Desire domain:
    - 0.3-0.4 on scale of 1.2-6.0.<sup>1-4</sup>
  - Number Needed to Harm (NNH) for any investigator defined adverse event =5, dizziness =10-15, somnolence =10-14, nausea =13-25, fatigue =29-42.<sup>3</sup>
  - US Food and Drug Administration (FDA) review (including unpublished data)<sup>5</sup> reports NNH for any serious adverse event =250, syncope =500.
  - Study limitations:
    - Strict exclusion criteria (example no benzodiazepines, sleep aids, narcotics, antidepressants).<sup>1-4</sup>
    - Change in primary outcome to find statistical significance.<sup>3,4</sup>
    - Poor adverse events and drug interactions reporting.<sup>1,2</sup>

### Context:

- FDA assessed phase 1-3 studies with 6,439 women reports safety concerns regarding hypotension, syncope, and somnolence, worsened with alcohol, oral contraceptives, and antifungals (among others).<sup>6</sup>
- Among 25 patients (23 male) given both alcohol (0.4g/kg) and flibanserin, 17% developed hypotension and/or syncope requiring intervention.<sup>6</sup>

- Following the second FDA rejection, an advocacy campaign entitled “Even the Score” (sponsored in part by flibanserin manufacturers) claimed the FDA was exhibiting gender bias by rejecting flibanserin.<sup>7,8</sup>
- FDA approved flibanserin for Hypoactive Sexual Desire Disorder on its third application, with a risk mitigation strategy including alcohol contraindication and further research.<sup>6,8,9</sup>
- Flibanserin has not yet been approved for use in Canada.

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#### Disclosure:

Authors do not have any conflicts to disclose.

#### References:

1. Thorp J, Simon J, Dattani D, *et al.* J Sex Med. 2012 Mar; 9(3):793-804.
2. Derogatis LR, Komer L, Katz M, *et al.* J Sex Med. 2012 Apr; 9(4):1074-85.
3. Katz M, DeRogatis LR, Ackerman R, *et al.* J Sex Med. 2013 Jul; 10(7):1807-15.
4. Simon JA, Kingsberg SA, Shumel B, *et al.* Menopause. 2014 Jun; 21(6):633-40.
5. FDA Briefing Document. Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management (DSaRM) Advisory Committee. June 4, 2015. Available at: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM449088.pdf>. Last accessed January 19, 2016.
6. Centre for Drug Evaluation and Research. Risk Assessment and Risk Mitigation Review(s) Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2015/022526Orig1s000RiskR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/022526Orig1s000RiskR.pdf). Last accessed January 19, 2016.
7. Even the Score [website]. <http://www.eventhescore.org>. Last accessed January 19, 2016.
8. Moynihan R. BMJ. 2014 Oct 17; 349:g6246.
9. Joffe HV, Chang C, Sewell C, *et al.* N Engl J Med. 2016 Jan 14; 374(2):101-4.

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