

Addyi (Flibanserin)

For premenopausal women who are very distressed by low sexual desire

Addyi Study Findings

FDA approved Addyi based on 3 six-month trials that had similar results. Results below are for the largest trial.

1087 women in stable relationships very distressed by at least 6 months of low desire - NOT caused by a medical condition, medications or relationship problems (average age 36 (19 to 55), had 2 satisfying sexual encounters a month) were given ADDYI or PLACEBO for 6 months. Here's what happened:

What difference did Addyi make?

Addyi
(100mg at night*)

PLACEBO
(No drug)

Did Addyi help?

Satisfying sexual encounters?

ADDYI increased the number of satisfying sexual encounters. (0.5 more satisfied encounters in a month)

1 more satisfying sexual encounter

0.5 more satisfying sexual encounters

More women were "much" or "very much" improved in satisfying sexual encounters. (9% more women)

31% of women

22% of women

Sexual desire?

More women were "much or "very much" improved in their distress about low desire. (9% more women)

34% of women

25% of women

ADDYI did NOT increase sexual desire scores reported in daily diaries in the 2 other trials.

Not measured in this trial

Did Addyi have side effects?

BLACK BOX WARNING - FDA's most serious side effect alert

Do not drink alcohol or take with any drugs that increase ADDYI blood levels (including some medications for HIV, fungal infections, Hepatitis C infection, high blood pressure or heart problems, nefazodone, and grapefruit juice), because the combination can cause **dangerously low blood pressure (hypotension)** and **fainting (syncope)**. People with liver disease should not take ADDYI since these problems are more likely.

Serious side effects

More women had **severe drowsiness** (13% more)

21%

8%

More had **dangerously low blood pressure** (0.2% more women)

0.2%

less than 0.1%

More **fainted** (0.2% more)

0.4%

0.2%

More had **appendicitis** (0.2% more)

0.2%

0%

Caused **breast cancers in mice** - uncertain whether increases breast cancer in women

Symptom side effects**

More had **dizziness** (9% more)

11%

2%

More had **nausea** (6% more)

10%

4%

More had **fatigue** (3% more)

9%

6%

More had **insomnia** (3% more)

5%

3%

More had **dry mouth** (1% more)

2%

1%

*Low blood pressure, fainting and drowsiness more likely if taken in day

**Based on all phase 3 trials with 1543 women taking Addyi for 6 months