"Female Viagra": Q&A with Ildiko Kovacs, MD

By Christina Johnson | November 02, 2015

he first FDA-approved medication to treat sexual dysfunction in women became available in October. Dubbed "pink Viagra" or "female Viagra," flibanserin (marketed as Addyi) treats low sex drive in premenopausal women.

The drug has a projected monthly price tag of \$400 and significant safety warnings. Controversy persists about its effectiveness and whether low libido is, in fact, a medical condition warranting pharmaceutical intervention. Advocates note that there are several medications on the market to treat sexual dysfunction in men, such as Viagra.



Ildiko Kovacs, MD, is a board-certified psychiatrist who specializes in caring for individuals and couples experiencing issues related to sexual function, sexuality and gender. Certified to prescribe Addyi, she talks about the new drug.

Question: How does Addyi work?

Answer: Addyi was originally developed and evaluated as an antidepressant. As such, it works by affecting the brain's chemical messengers. It has a unique mechanism of action that increases levels of the neurotransmitters dopamine and norepinephrine while decreasing serotonin. In some women, this enhances sexual responsiveness and motivation. Unlike Viagra, it is not taken on

demand. Patients need to take Addyi nightly for about 4 weeks, with results peaking around 8 weeks of treatment. If there is no improvement at that point, then further treatment is not likely to produce significant benefit and the medication can be discontinued.

Q: What can women expect?

A: In clinical trials, women who took the 100 mg bedtime dose of Addyi reported increased interest in sexual activity, more sexually satisfying events and less distress, but the changes were gradual and incremental. Long term studies – 12 months – showed sustained benefit.

Q: Why would an antidepressant increase a person's sex drive?

A: In general, antidepressants that increase serotonin levels in the brain tend to have negative sexual side effects. Addyi does the opposite while also increasing sex-positive dopamine and norepinephrine levels.

Q. What is the definition of low sex drive? In other words, who is a candidate for going on Addyi?

A: Hypoactive sexual desire disorder (HSDD) is the clinical diagnosis and it refers to patients who have experienced low desire for more than 6 months with significant distress or interpersonal difficulties. These individuals have no interest in sex, no sexual fantasies and they rarely initiate sex. If they engage in sex – maybe out of duty, expression of love or fear of losing their partner – it causes stress and anxiety. To make the diagnosis of HSDD, we must rule out other factors that might cause low desire, such as certain medications, depression, anxiety, hormonal imbalances and relationship problems, just to mention a few. If there are no identifiable explanations for low desire, HSDD is diagnosed and Addyi might be a treatment option for premenopausal women. About 10 percent of premenopausal women are believed to have HSDD.

Q: Why is Addyi approved for premenopausal women only?

A: After menopause, sex drive may naturally decrease due to hormonal declines and the aging process. The wide variation in how women experience menopause, however, creates a diverse patient group. As a result, the FDA is requiring more studies before it will approve the medication for postmenopausal women. That said, there is no reason why Addyi should work differently for postmenopausal women but insurance companies will not cover such "off-label" use.

Q: Why is it unsafe to drink alcohol on Addyi? Are there other contra-indications?

A: Based on extensive studies, the FDA recommends completely avoiding alcohol while on Addyi because of the potential for women to experience a sudden drop in blood pressure that can possibly cause fainting. This is a rare side effect but of serious enough concern that only certified physicians and pharmacies can prescribe and dispense Addyi. To maintain our certification, we must document our patient education on the dangers of combining Addyi and alcohol. Other potential side effects include dizziness, sleepiness, nausea and fatigue. Addyi should not be taken in combination with other antidepressants.

Q: Why has been so much controversy surrounding this drug?

A: Several perspectives are at play. For one, there is no agreement on what is a normal sex drive for women. Some critics feel that HSDD is an artificial diagnosis that inappropriately categorizes lower spontaneous sexual desire as a disorder rather than a normal variant. Others believe that even though Addyi was more effective than a placebo in studies, the results were not robust enough to justify the potential side effects and unrealistic restrictions, such as no alcohol. Another factor is that it is very difficult to quantify positive sexual experiences in women, as it does not always equate with the number of orgasms. A new concept called sexually satisfying experience

was defined and used in the studies to measure and show effectiveness of the drug. Some experts also believe that the FDA was pressured by activist groups and a big PR campaign to approve Addyi just to have a medication finally available for female sexual problems. We also don't know if Addyi is more effective than a short course of sexual counseling, which can provide long-term benefits without side effects. We are all hoping that the approval of Addyi will inspire a more open discussion and understanding of female sexual problems, leading to a range of new treatments.

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