FLIBANSERIN (Addyi) Fact Sheet

Bottom Line:

Flibanserin, marketed as the "pink Viagra," is mildly effective for enhancing sexual desire, but with potentially significant side effects and precautions regarding alcohol use around the time of administration.

FDA Indications:

Hypoactive sexual desire disorder in premenopausal women.

Dosage Forms: Tablets: 100 mg.

Dosage Guidance:

Start and continue 100 mg QHS; taking during the daytime may increase risk of hypotension, syncope, and CNS depression. Discontinue after eight weeks if no improvement.

Monitoring: No routine monitoring recommended unless clinical picture warrants.

Cost: \$\$\$\$\$ **Side Effects:**

- Most common: Dizziness, somnolence, nausea, fatique, insomnia, dry mouth.
- Serious but rare: May have potential to cause severe hypotension or syncope.
- Pregnancy/breastfeeding: Not enough data to recommend.

Mechanism, Pharmacokinetics, and Drug Interactions:

- Mixed agonist-antagonist on postsynaptic serotonergic receptors with 5-HT1A agonist and 5-HT2A antagonist
- Metabolized primarily through CYP3A4 and to a lesser extent 2C19; t ½: 11 hours.
- Avoid concomitant use with alcohol, with CYP3A4 inhibitors, or in patients with hepatic impairment as there may be an increased risk for hypotension and syncope.

Clinical Pearls:

- Flibanserin has not been studied in postmenopausal women or in men.
- Flibanserin does not enhance sexual performance; rather, it increases interest.
- While studies of Viagra show around 80% of men improving (50%-60% more than placebo), only 8%-13% more women on flibanserin had benefits over placebo.
- The manufacturer wanted the black box warning and contraindication about alcohol removed, so the FDA reviewed postmarketing studies. Rather than remove the warning, the FDA decided to modify it. They determined that there is still cause for concern about drinking alcohol close in time to taking flibanserin but that it doesn't have to be avoided completely. Now the warning specifies that women shouldn't drink two hours before or at least until the morning after taking flibanserin at bedtime.

Based on mediocre efficacy data, Dr. Carlat has made the analogy that "if Viagra is a Starbucks triple espresso, flibanserin is a Dixie cup of cafeteria coffee."

