

## New Drug for Erectile Dysfunction

### Erectile dysfunction medication Stendra just approved by FDA



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The medication Stendra (avanafil) has just been approved by the U.S. Food and Drug Administration to treat erectile dysfunction, the FDA announced today.

Approximately 30 million men in the U.S. have difficulty getting or maintaining an erection, according to the FDA's release. This inability to have a satisfactory sex life can negatively impact a person's quality of life and personal relationships.

"This approval expands the available treatment options to men experiencing erectile dysfunction, and enables patients, in consultation with their doctor, to choose the most appropriate treatment for their needs," said Victoria Kusiak, M.D., deputy director of the Office of Drug Evaluation III in the FDA's Center for Drug Evaluation and Research.

The approval comes following the FDA's review of three different clinical studies involving 1,268 patients that showed Stendra's effectiveness.

For 12 weeks, patients were randomly assigned to take a 50mg, 100mg or 200mg dose of Stendra, or else a placebo, as they found necessary approximately 30 minutes before having sex.

The participants filled out surveys at the beginning of the trial and every four weeks about their erections, ability to penetrate the vagina and the ability to successfully have intercourse.

All three groups who took the Stendra showed an improvement in erectile function by the end of the

study that was significantly greater than the placebo group.

According Ashley Buford, a spokesperson for California-based manufacturer Mountain View of VIVUS Inc., Stendra is an "important new option" for men to consider for erectile dysfunction treatment because of it's "rapid absorption and selectivity profile."

"The 30-minute dosing instructions prior to sexual activity are unique," she said.

Viagra, Cialis and Levitra, the other three drugs prescribed for erectile dysfunction, are supposed to be taken 30 minutes to one hour before sexual activity. The manufacturer website for Viagra, for example, states that it begins to work for most men in 30 to 60 minutes.

Stendra is supposed to be taken about 30 minutes before sexual intercourse, but some patients in the clinical trials could have sex as soon as 15 minutes, said Parviz Kavoussi, M.D., a urologist at Austin Fertility & Reproductive Medicine in Austin, Texas.

"The question is, how important is this time frame? Only the individual couple can answer that," Dr. Kavoussi said. "The potential advantage is that it requires less planning and does not cause as much of an interference with spontaneity."

Dr. Kavoussi offered a more detailed comparison of Stendra with Cialis, the only other drug that has a product aiming to get around the spontaneity issue.

"It would seem that Cialis has already considered this concern by providing the daily dose," he said. "Stendra offers an on-demand dose that does not require daily use with what potentially may be a faster acting drug."

Ultimately, the value of Stendra will depend on its price compared to its competitors.

"It may be a good option if the price is right," Dr. Kavoussi said. "Otherwise, individual men will have to decide how much the possibility of waiting that extra 15 to 45 minutes is worth to them out of their

pocketbooks."

Stendra is a type of drug called a phosphodiesterase type 5 (PDE5) inhibitor, which help increase blood flow to the penis. If a man is taking nitrates, often prescribed for chest pain, he should not also take a PDE5 inhibitor because taking the two medications together can lead to a sudden drop in blood pressure.

Overall, the drug was well tolerated, Buford said on behalf of the manufacturer, which means that the men as a whole did not experience many problems with the drug.

Side effects of Stendra can include color vision changes, but the more common side effects that occurred in over 2 percent of the clinical trial patients included headache, back pain, cold symptoms, nasal congestion and redness in the face.

If a man taking Stendra experiences an erection that lasts four hours or longer and will not go away, as can happen in very rare cases, he should seek immediate medical care.

A more serious side effect is loss of vision in one or both eyes. If this occurs to someone, he should immediately stop taking Stendra and/or any other PDE5 inhibitor and contact his doctor.

According to VIVUS Inc. spokesperson Buford, the cost for Stendra has not yet been determined.

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Parviz Kavoussi, M.D.



Parviz Kavoussi, M.D. is an expert in erectile dysfunction, sexual medicine and male infertility. He is in practice with his infertility specialist father and brother where they pride themselves in being a family that helps others start their families.

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