FDA NEWS

FDA: Prasterone therapy approved for vulvar, vaginal atrophy

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The FDA today approved prasterone for treatment of moderate to severe pain during sexual intercourse, a symptom of vulvar and vaginal atrophy, in postmenopausal women, according to an FDA press release.

Efficacy of prasterone (Intrarosa, Endoceutics Inc.), also known as dehydroepiandrosterone or DHEA, in a once-daily vaginal insert, was demonstrated through two 12-week placebo-controlled clinical trials that included 406 healthy postmenopausal women randomly assigned to prasterone or placebo. Prasterone significantly reduced the severity of pain during sexual intercourse compared with placebo, according to the release. The most commonly reported adverse events included vaginal discharge and abnormal Pap smear.

“Pain during sexual intercourse is one of the most frequent symptoms of [vulvar and vaginal atrophy] reported by postmenopausal women” **Audrey Gassman, MD,** deputy director of the division of bone, reproductive and urologic products in the office of drug evaluation III in the FDA’s Center for Drug Evaluation and Research, said in the release. “Intrarose provides an additional treatment option for women seeking relief for dyspareunia caused by [vulvar and vaginal atrophy].”