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FDA OKs Prasterone for Dyspareunia in Postmenopausal Women

Megan Brooks | November 17, 2016

The US Food and Drug Administration (FDA) has approved prasterone (*Intrarosa*, Endoceutics Inc) to treat women with moderate to severe pain during sexual intercourse (dyspareunia) associated with menopause.

Prasterone, a once-daily vaginal insert, is the first FDA-approved product containing the active ingredient prasterone, also known as dehydroepiandrosterone (DHEA).

Estrogen levels decline in vaginal tissues during menopause, which may lead to vulvar and vaginal atrophy (VVA) and contribute to pain during sexual intercourse.

"Pain during sexual intercourse is one of the most frequent symptoms of VVA reported by postmenopausal women. Intrarosa provides an additional treatment option for women seeking relief of dyspareunia caused by VVA," Audrey Gassman, MD, deputy director of the Division of Bone, Reproductive and Urologic Products, in the FDA's Center for Drug Evaluation and Research, said in a statement.

According to the FDA, the efficacy of Intrarosa was demonstrated in two 12-week placebo-controlled clinical trials involving 406 healthy postmenopausal women reporting moderate to severe pain during sexual intercourse as their most bothersome symptom of VVA.

Participants were randomly assigned to receive Intrarosa or a placebo vaginal insert. "Intrarosa, when compared to placebo, was shown to reduce the severity of pain experienced during sexual intercourse," the FDA said.

In addition, four 12-week placebo-controlled trials and one 52-week open-label trial established the safety of Intrarosa, the agency said. The most common adverse reactions with Intrarosa are vaginal discharge and abnormal Papanicolaou smear.

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