Newsmax

FDA OK's Remedy That Treats Women's Pain During Sex

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The U.S. Food and Drug Administration (FDA) has approved Intrarosa (prasterone), a medication that treats women who experience pain during sexual intercourse.

The medication, 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), which contribute to pain during sexual intercourse.

Vaginal atrophy is the thinning, drying and inflammation of the vaginal walls due to the decrease of estrogen that occurs after menopause.

Intrarosa provides an additional treatment option for women seeking relief of dyspareunia caused by VVA," Dr. Audrey Gassman, 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. Dyspareunia is the medical term for pain during intercourse.

According to the FDA, the efficacy of Intrarosa was demonstrated in two 12-week placebo-controlled clinical trials involving 406 healthy postmenopausal women, who reported moderate to severe pain during sexual intercourse.

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 says.

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 Pap smear readings, the studies show.

DHEA, a hormone manufactured by the body, boosts estrogen production.

Although this hormone is included in some dietary supplements, the efficacy and safety of those products have not been established for diagnosing, curing, mitigating, treating or preventing any disease, the FDA says.