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Intrarosa Approved by FDA For Postmenopausal Women Who Experience Pain During Sex

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The FDA announced earlier today that is has approved Endoceutics's drug Intrarosa (prasterone) to treat sexual pain associated with vulvar and vaginal atrophy (VVA).

The once-daily vaginal insert was found effective in a pair of previous placebo-controlled 12 week trials, with women reporting it decreased severity of pain from sex. VVA is thought to be caused by decreased levels of estrogen in vaginal tissue as a result of menopause. VVA can cause pain during and after sexual intercourse, a condition called dyspareunia.

Four additional 12-week placebo-controlled trials and one yearlong open-label trial established Intrarosa's safety. Adverse effects described in those studies were abnormal Pap smear and vaginal discharge.

The active ingredient in Intrarosa, prasterone, is also called dehydroepiandrosterone (DHEA) and is used in some dietary supplements. According to the FDA's official announcement, "the efficacy and safety of those products have not been established for diagnosing, curing, mitigating, treating or preventing any disease."

This is the first FDA-approved product containing DHEA.

Audrey Gassman, M.D., of the Division of Bone, Reproductive, and Urologic Products (DBRUP) at the FDA called Intrarosa "an additional treatment option for women seeking relief of dyspareunia caused by VVA."

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