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FDA Approves Intrarosa for Sexual Symptoms of Menopause

— Product contains DHEA as active ingredient

by Molly Walker
Staff Writer, MedPage Today

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WASHINGTON -- The FDA approved prasterone (Intrarosa), a once-daily vaginal insert designed to help alleviate moderate or severe pain during sexual intercourse in post-menopausal women.

This is the first product approved to treat sexual symptoms of menopause that contains the active ingredient, prasterone -- also known as dehydroepiandrosterone (DHEA), a dietary supplement that has been previously found to help treat sexual dysfunction associated with menopause.

However, the FDA noted in its announcement of the prasterone approval that the safety and efficacy of over-the-counter DHEA "has not been established for diagnosing, curing, mitigating, treating, or preventing any disease." The Intrarosa approval is the FDA's first for any DHEA-containing product.

A decline in estrogen in vaginal tissues during menopause can lead to vulvar and vaginal atrophy (VVA), which in turn can cause dyspareunia, or pain during intercourse, the FDA said.

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

Intrarosa (manufactured by Quebec-based Endoceutics) was found to decrease severity of pain during intercourse in two 12-week placebo-controlled trials of women with moderate

to severe dyspareunia. Women were ages 40 to 80 and received either Intrarosa or placebo. Safety was established in four 12-week trials and one 52-week open-label trial.

The FDA noted that the most common adverse reactions were vaginal discharge and abnormal Pap smear.