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FDA Approves Intrarosa for the Treatment of Dyspareunia

Intrarosa is the first approved drug containing prasterone

The Food and Drug Administration (FDA) has approved Intrarosa (prasterone; Endoceutics) for the treatment of women experiencing moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

Intrarosa, a once-daily vaginal insert, is the first approved drug containing prasterone, also known as dehydroepiandrosterone (DHEA).

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- Osphena Approved for Dyspareunia
- Phase 3 study of Ophena for treatment of dyspareunia associated with postmenopausal vaginal atrophy

The efficacy of Intrarosa was established in two 12-week placebo-controlled trials (n=406) of healthy postmenopausal women aged 40–80 years. They cited moderate to severe pain during sexual intercourse as the most bothersome symptom of vulvar and vaginal atrophy. Study participants were randomized to either Intrarosa or a placebo vaginal insert. Women who received Intrarosa had a reduced severity of pain experienced during sexual intercourse compared to the placebo group.

The safety of Intrarosa was established in four 12-week placebo-controlled trials and one 52-week open-label trial. Vaginal discharge and abnormal Pap smear were reported as the most common adverse reactions.

For more information call (855) 653-0033 or visit Endoceutics.com.

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