The Clinical Advisor

Colby Stong, Editor

December 05, 2016

FDA approves new drug for postmenopausal pain during sex

Share this content:

- facebook
- twitter
- linkedin
- google
- Comments
- Print

The FDA has approved Intrarosa (prasterone), a once-daily vaginal insert, for women who have moderate to severe pain during sexual intercourse due to menopause. It is the first FDA-approved product that contains the active ingredient prasterone (dehydroepiandrosterone).

Intrarosa provides an additional treatment option for women with dyspareunia caused by vulvar and vaginal atrophy.

The efficacy of Intrarosa (Endoceutics Inc) was established in two 12-week, placebo-controlled clinical trials of 406 healthy postmenopausal women (aged 40 to 80 years), who reported moderate to severe pain during sexual intercourse as their most bothersome symptom of vulvar and vaginal atrophy. The women were randomly assigned to receive Intrarosa or a placebo vaginal insert. Compared with placebo, Intrarosa reduced the severity of pain experienced during sexual intercourse.

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

Reference

1. US Food and Drug Administration. FDA approves Intrarosa for postmenopausal women experiencing pain during sex [press release]. November 17, 2016. Accessed December 5, 2016.