Intrarosa (prasterone)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Intrarosa
- **Generic name:** Prasterone
- **Pharmacological class:** Steroid
- **Strength and Formulation:** 6.5mg; per vaginal insert
- **Manufacturer:** AMAG Pharmaceuticals
- **How supplied:** Blister pack—28 (w. applicators)
- **Legal Classification:** Rx

Indications

- Moderate-to-severe dyspareunia due to menopause

Dosage & Administration

- Use 1 vaginal insert once daily at bedtime

Considerations for Special Populations

- **Pregnancy:** Only indicated for post-menopausal women
- **Nursing mothers:** Only indicated for post-menopausal women
- **Pediatric:** Not established
- **Hepatic or renal impairment:** Not studied

Contraindications

- Undiagnosed abnormal genital bleeding

Warnings/Precautions

- Breast cancer or history of
- Evaluate undiagnosed, persistent or recurrent genital bleeding prior to initiation
- Premenopausal: not indicated

Adverse Reactions

- Vaginal discharge
- Abnormal Pap smear

Mechanism of Action

- **Prasterone** is an inactive endogenous steroid and is converted into active androgens and/or estrogens
- Its mechanism of action in post-menopausal women with vulvar and vaginal atrophy is not fully established

Clinical Studies

- Intrarosa was studied in two primary 12-week, randomized, double-blind, placebo controlled efficacy trials (**Trial 1** and **Trial 2**)
- **Trial 1** (n=255) enrolled healthy post-menopausal women aged 40–75 years who, at baseline, identified moderate to severe dyspareunia as their most bothersome symptom of vulvar and vaginal atrophy

Clinical Studies

- The 4 **co-primary efficacy endpoints** were:
  - Most bothersome moderate to severe symptom of dyspareunia
  - Percentage of vaginal superficial cells
  - Percentage of parabasal cells
  - Vaginal pH

Clinical Studies

- Patients were randomized to receive Intrarosa (n=87), active comparator vaginal insert (n=87), or placebo (n=81)
- The Intrarosa arm showed a greater change in **mean severity** of dyspareunia from Baseline to Week 12 compared to placebo (-1.27 vs. -0.87; *P*<0.0132)

Clinical Studies

- There was a greater change in the percent of **superficial cells** (5.62 vs. 0.91; *P*<0.0001) and **parabasal cells** (-47.40 vs. -1.62; *P*<0.0001) with Intrarosa vs. placebo
- Intrarosa was also superior in the mean change of **vaginal pH** (-1.04 vs. -0.21; *P*<0.0001) vs. placebo

Clinical Studies

- **Trial 2** (n=558) enrolled healthy postmenopausal women aged 40–80 years old
- Patients were randomized to receive Intrarosa (n=376) or placebo (n=182)

Clinical Studies

- Primary end points for Trial 2 were the same or similar to those of Trial 1
- The Intrarosa arm showed a greater change in **mean severity** of dyspareunia from Baseline to Week 12 compared to placebo (-1.42 vs. -1.06; P<0.0002)

Clinical Studies

- There was a greater change in the percent of **superficial cells** (10.20 vs. 1.75; *P*<0.0001) and **parabasal cells** (-41.51 vs. -11.98; *P*<0.0001) with Intrarosa vs. placebo
- Intrarosa was also superior in the mean change of **vaginal pH** (-0.94 vs. -0.27; *P*<0.0001) vs. placebo

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/intrarosa/drug/34689/