Intrarosa (prasterone)
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
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.
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.
For more information view the product monograph available at:

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