FULL PRESCRIBING INFORMATION: CONTENTS*

1. INDICATIONS AND USAGE

INTERRASA® is a sealed individual for the treatment of moderate to severe dyspareunia, a symptom of vaginal and cervical atrophy, due to menopause.

2. DOSAGE AND ADMINISTRATION

Administer one INTERRASA vaginal insert once daily at bedtime, using the provided applicator.

3. DOSAGE FORMS AND STRENGTHS

Vaginal insert: 6.5 mg of prostaglandin, ointment, white to off-white solid bullet-shaped, measuring 28 mm in length, 9 mm in width at its wider end, and weighing 1.2 g.

4. CONTRAINDICATIONS

Unrecognized abnormal genital bleeding: Any patient receiving oestrogens with unrecognized persistent or recurrent vaginal bleeding should be evaluated to determine the cause of the bleeding before considering treatment with INTERRASA®.

5. WARNINGS AND PRECAUTIONS

5.1 Current or Past History of Breast Cancer

Estrogen is a metabolite of oestrogen and oestrogen use has been implicated in women with a known or suspected history of breast cancer. INTERRASA® has not been studied in women with a history of breast cancer.

5.2 ADVERSE REACTIONS

5.2.1 Clinical Trials Experience

During clinical trials were conducted under widely varying conditions, adverse reactions in the placebo group were generally considered to have been related to the effects of the active ingredients in the placebo group. The incidence of adverse effects was generally less than 1%. The adverse reactions associated with the use of INTERRASA® in vivo are generally similar to those seen with other progestins and similar medications.

5.2.2 Clinical Studies

5.3.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate carcinogenic potential have not been conducted with progestins. The carcinogenic potential of progestins, testosterone and estradiol is unknown in animals.

6. USE IN SPECIFIC POPULATIONS

6.1 Pregnancy

INTERRASA® is contraindicated only in postmenopausal women. There is no data with INTERRASA® use in pregnant women regarding its potential effects. Animal reproduction studies have not been conducted with progestins.

6.2 Lactation

INTERRASA® is contraindicated only in postmenopausal women. There is no information on the presence of progestins in human milk. No effects were observed in the breastfed infants of rats exposed to INTERRASA® in vivo.

6.4 Pediatric Use

The effectiveness of INTERRASA® on moderate to severe dyspareunia, a symptom of vaginal and cervical atrophy, due to menopause was evaluated in two primary placebo-controlled trials.

The first primary trial (Trial 1) was a 12-week randomized, double-blind placebo-controlled trial that enrolled 181 postmenopausal women randomly assigned to one of the following treatments: placebo, INTERRASA® (1.0 mg) or INTERRASA® (3.0 mg). Women were randomized in a 1:1:1 ratio between these three treatment groups who received daily INTERRASA® (0.1 mg), 0.1 mg to 0.01 mg progestin (i.e., 0.01 mg progestin or placebo). All women were assessed for improvement from baseline at Week 12 for cervical effusions, vaginal effusions, and vaginal discharge. Between the two treatments, there were no significant differences observed in any of these parameters.

In the second primary trial (Trial 2) which was a 32-week randomized, double-blind placebo-controlled trial that enrolled 253 postmenopausal women randomly assigned to one of the following treatments: placebo, INTERRASA® (1.0 mg) or INTERRASA® (3.0 mg). Women were randomized in a 2:1:1 ratio to receive daily vaginal insert containing 6.5 mg INTERRASA® (0.01 mg) or placebo (0.01 mg). The primary endpoints and study was evaluated the same or similar to those in Trial 1.

The primary efficacy results obtained in the INTERRASA® (0.01 mg) population in Table 2 are shown in Table 3.
**Patient Information**

**INTRAROSA® (In trah ROE siah)**
(prasterone) vaginal inserts

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**What is INTRAROSA vaginal inserts?**

INTRAROSA vaginal inserts are a prescription medicine used in women after menopause to treat moderate to severe pain during sexual intercourse caused by changes in and around the vagina that happen with menopause. It is not known if INTRAROSA vaginal inserts are safe and effective in children.

**Do not use INTRAROSA vaginal inserts** if you have vaginal bleeding that has not been checked by your healthcare provider.

**Before using INTRAROSA vaginal inserts**, tell your healthcare provider about all of your medical conditions, **including**:

- have, have had, or think you may have had breast cancer. Prasterone, an ingredient in INTRAROSA vaginal inserts, is changed in your body to estrogen. Estrogen medicines are not for use in women who have, have had, or think they may have had breast cancer.
- are pregnant or plan to become pregnant. INTRAROSA is only for use in women who are past menopause. It is not known if INTRAROSA vaginal inserts will harm your unborn baby.
- are breastfeeding or plan to breastfeed. INTRAROSA vaginal inserts are only for use in women who are past menopause. It is not known if INTRAROSA passes into your breast milk.

**Tell your healthcare provider** about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I use INTRAROSA vaginal inserts?**

- See the Instructions for Use at the end of this Patient Information for detailed instructions about the right way to use INTRAROSA vaginal inserts.
- Use INTRAROSA vaginal inserts exactly how your healthcare provider tells you to use it.
- Place 1 INTRAROSA vaginal insert in your vagina one time each day at bedtime, using the applicator that comes with INTRAROSA vaginal inserts.