Not sure how to start the conversation? Whether you prefer to be direct or more discreet, here are a few ideas:

- I’ve been having pain during sex
- I have some vaginal symptoms I’d like to discuss
- Sometimes when I’m intimate with my partner, I have pain

Here are 5 questions to help guide the discussion:

1. Why am I having painful sex after menopause?
2. What happens if I choose not to treat it? Will the pain go away on its own or will it get worse?
3. Would INTRAROSA be a potential treatment option for me?
4. How should I use INTRAROSA and do I use it every day?
5. What are the possible side effects of INTRAROSA?

Tips from your healthcare provider:

- Give us time for a good discussion. Instead of waiting for your next well visit, make a special appointment.
- If you do wait for a well visit, bring it up at the start of the appointment.
- Do a little bit of research before your appointment and come with a list of questions that are most important to you.

For help starting the conversation with your healthcare provider about moderate to severe painful sex after menopause, print this page and take it to your next appointment.

Indication
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.

Important Risk Information
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 if you:
- 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.

The most common side effects of INTRAROSA vaginal inserts are vaginal discharge and changes on Pap smear.

These are not all of the possible side effects of INTRAROSA vaginal inserts.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit fda.gov/medwatch or call 1-800-FDA-1088.

Please see following pages for full Prescribing Information.
**INDICATIONS AND USAGE**

INTRAROSA (prasterone) vaginal insert is a vaginal application for the treatment of moderate to severe vulvar and vaginal atrophy, due to menopause.

**DOSAGE AND ADMINISTRATION**

Administer one INTRAROSA vaginal insert once daily at bedtime, into the posterior aspect of the vagina.

**CONTRAINDICATIONS**

INTRAROSA is contraindicated in women with a history of breast cancer, endometrial cancer, or if the tumor is estrogen dependent.

**WARNINGS AND PRECAUTIONS**

Use INTRAROSA with caution in women with a personal or family history of breast cancer, or who have a disease or condition that may be amplified by estrogen use.

**ADVERSE REACTIONS**

The clinical trials were conducted in healthy postmenopausal women between 40 to 80 years of age who were postmenopausal for at least 1 year, were within 2 years of menopause, and had a duration of menstrual bleeding of ≤28 days. The most common adverse reactions (≥2%) were vaginal discharge, accidental intercourse, and abdominal pain.

**DESCRIPTION**

INTRAROSA (prasterone) vaginal insert is a vaginally administered formulation containing 6.5 mg of prasterone, a progestational steroid that is a metabolite of androstenedione and/or androstosterone. It is a white to off-white crystalline solid with a molecular weight of 288.424 g/mol. Prasterone is a white to off-white crystalline solid and has a theoretical purity of 99.94%.

**CLINICAL PHARMACOLOGY**

**Metabolism**

In one in vivo efficacy trial, daily administration of INTRAROSA was associated with an increase in mean total estradiol (all estradiols measured) of 12.44 pg/mL (±1.28) compared to placebo (mean ± S.D.). This increase is consistent with an increase in estradiol levels observed in clinical trials of another drug.

**Pharmacokinetics**

**Pregnancy**

No data with INTRAROSA use in pregnant women regarding pregnancy outcomes are available. Pregnancy studies were not conducted with prasterone.

**NURSING MOTHERS**

It is not known if prasterone is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when INTRAROSA is administered to a nursing mother.

**LACTATION**

There are no data with INTRAROSA use in breastfeeding women regarding effects on the breastfed infant, or the effects on milk production.

**DOSAGE AND STRENGTHS**

Vaginal Insert: 6.5 mg of prasterone, smooth, white to off-white solid dialectic gel (Hithemol®) weighing 1.2 gram.

**DEFINITIONS**

Abnormal vaginal bleeding: postmenopausal women with abnormal vaginal bleeding who were treated with INTRAROSA with an incidence of >2% - “Other” women, average age 57.9 years (range 43 to 80 years)

**ADVERSE DRUG REACTIONS**

**In women**

In the low-dose arm of the clinical trial, INTRAROSA was associated with an increase in mean vaginal atrophy (mean ± S.D.). This increase is consistent with an increase in estradiol levels observed in clinical trials of another drug.

**In men**

In one in vivo efficacy trial, daily administration of INTRAROSA was associated with an increase in mean total estradiol (all estradiols measured) of 12.44 pg/mL (±1.28) compared to placebo (mean ± S.D.). This increase is consistent with an increase in estradiol levels observed in clinical trials of another drug.
INTRAROSA vaginal inserts should be stored at room temperature and kept out of reach of children.

Instructions for Use

INTRAROSA vaginal inserts are supplied as a prescription medication 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 other uses.

Before using INTRAROSA vaginal inserts, tell your healthcare provider about all of your medical conditions, including: if you: • have ever had or if you have breast cancer. • have or had, or think you may have had breast cancer. • are breastfeeding or plan to breastfeed. INTRAROSA vaginal inserts will harm your unborn baby. Do not use INTRAROSA vaginal inserts for use in women who are past menopause. It is not known if INTRAROSA vaginal inserts will harm your unborn baby. Do not give INTRAROSA vaginal inserts to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about INTRAROSA vaginal inserts.

What are the ingredients in INTRAROSA vaginal inserts?

• Inactive ingredient:
  - prasterone
  - off-white hard fat (Witepsol)

• Active ingredient:
  - prasterone

What are the possible side effects of INTRAROSA vaginal inserts?
The most common side effects of INTRAROSA vaginal inserts are vaginal discharge and changes on Pap smear. These are not all of the possible side effects of INTRAROSA vaginal inserts.

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

How should I use INTRAROSA vaginal inserts?

For detailed instructions about the right way to use INTRAROSA vaginal inserts, see “How Supplied/Storage and Handling.”

How should I store INTRAROSA vaginal inserts?

• Store INTRAROSA vaginal inserts between 41°F to 86°F (5°C to 30°C).

• Place 1 INTRAROSA vaginal insert in your vagina one time each day at bedtime.

• Use INTRAROSA vaginal inserts exactly how your healthcare provider tells you to use it.

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• Place 1-877-411-2510.

For more information, go to www.intrarosa.com or call 1-877-411-2510.

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