

Patient Information
INTRAROSA™ (in trah ROE sah)
(prasterone) vaginal inserts

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 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.
- 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.

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.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store INTRAROSA vaginal inserts?

- Store INTRAROSA vaginal inserts between 41°F to 86°F (5°C to 30°C).
- INTRAROSA vaginal inserts can be stored at room temperature or in the refrigerator.

Keep INTRAROSA vaginal inserts and all medicines out of the reach of children.

General Information about the safe and effective use of INTRAROSA vaginal inserts.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INTRAROSA vaginal inserts for a condition for which it was not prescribed. 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 that is written for health professionals.

What are the ingredients in INTRAROSA vaginal inserts?

Active ingredient: prasterone

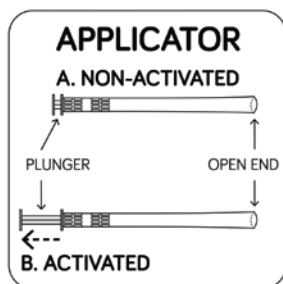
Inactive ingredient: off-white hard fat (Witepsol)

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

Instructions for Use
INTRAROSA (in trah ROE sah)
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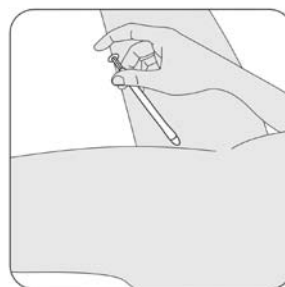
How should I use INTRAROSA vaginal inserts?

- INTRAROSA is a vaginal insert that you place in your vagina with an applicator that comes with INTRAROSA vaginal inserts.
- Use 1 INTRAROSA vaginal insert, one time each day at bedtime.
- Each applicator is for one time use only.
- Empty your bladder and wash your hands before handling the vaginal insert and applicator.
- Tear off 1 vaginal insert along the perforations from the 7-vaginal insert strip.



STEP 1

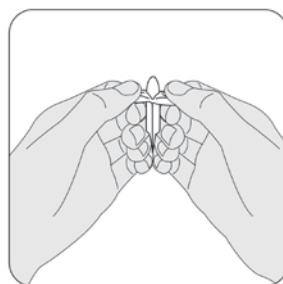
- 1a. Remove 1 applicator from the package.
- 1b. Pull back on the plunger until it stops to activate the applicator. The applicator must be activated before use. Place the applicator on a clean surface.



STEP 5

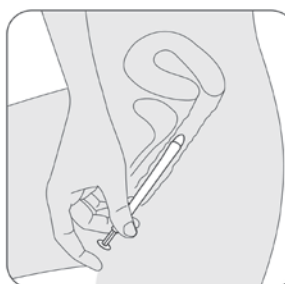
Select the position for insertion of the vaginal insert that is most comfortable for you.

5a. Lying position

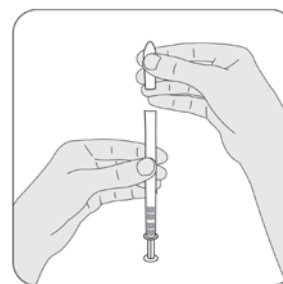


STEP 2

Slowly pull the plastic tabs on the vaginal insert away from each other while keeping the vaginal insert still between your fingers. Carefully remove the vaginal insert from the plastic wrap. If a vaginal insert falls on an unsanitary surface, replace it with a new one.

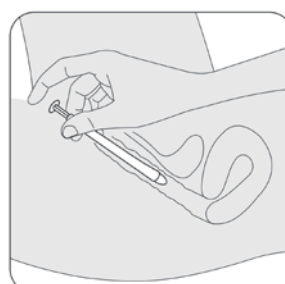


5b. Standing position



STEP 3

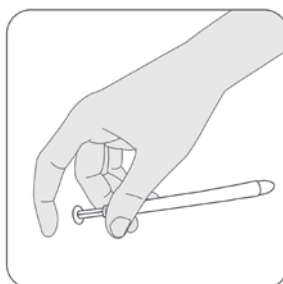
Place the flat end of the vaginal insert into the open end of the activated applicator as shown. You are now ready to insert the vaginal insert into your vagina.



STEP 6

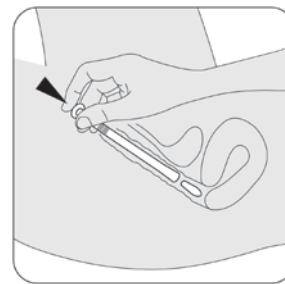
Gently slide the vaginal insert into your vagina as far as it will comfortably go.

Do not use force.



STEP 4

Hold the applicator between your thumb and middle finger. Leave your index (pointer) finger free to press the applicator plunger after the applicator is inserted into your vagina.



STEP 7

Press the applicator plunger with your index (pointer) finger to release the vaginal insert. Remove the applicator and throw it away after use.

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

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

INTRAROSA™ is a trademark owned by Endoceutics, Inc.

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