

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE



Prasterone Vaginal Ovules

Read this carefully before you start taking **Intrarosa**® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Intrarosa**®.

What is Intrarosa® used for?

- Intrarosa® is used to treat postmenopausal women with vulvovaginal atrophy.
- At menopause, there can be a lack of sex hormones. This may cause the tissues of the vulva and vagina to become thin and dry. Below are the possible symptoms:
 - vaginal dryness.
 - pain during sexual activity.
 - irritation.
 - itching.

How does Intrarosa® work?

Prasterone is used to make sex hormones in the vagina. After menopause, prasterone is the main source of sex hormones. This medicine replaces the natural sex hormones that are missing in some women. It may improve the symptoms of vulvovaginal atrophy.

What are the ingredients in Intrarosa®?

Medicinal ingredients: Prasterone

Non-medicinal ingredients: Hard fat

Intrarosa® comes in the following dosage forms:

Vaginal ovule 6.5 mg

Intrarosa® comes in blister packs of 28. There are 6 reusable applicators in the pack. You can reuse each applicator for up to one week (two extra applicators are provided in case you need them).

Do not use Intrarosa® if:

- You have an allergy to any of the ingredients of this drug or the container.
- You have vaginal bleeding that has not been diagnosed.
- You still have periods. This drug is for postmenopausal women only.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Intrarosa®. Talk about any health conditions or problems you may have, including if you:

- have a vaginal infection. The infection will need to be treated with antibiotics before starting treatment with Intrarosa®.
- have abnormal vaginal discharge.
- have a history of breast cancer.
- can get pregnant.
- are breast-feeding.

Other warnings you should know about:

- Go for regular Pap tests, gynecological and breast exams. Do this as per your healthcare professional's directions.
- If you get pregnant, stop taking Intrarosa®. Talk with your healthcare professional.
- You must call your healthcare professional if you have vaginal bleeding while on Intrarosa®.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Intrarosa®:

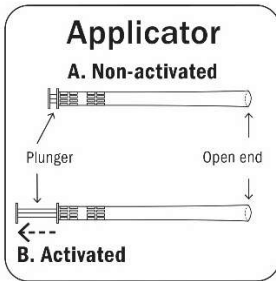
- Interactions with other drugs have not been established.

Intrarosa® can weaken condoms, diaphragms or cervical caps. This occurs if they are made of latex.

How to take Intrarosa®:

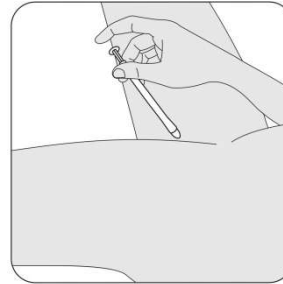
- Intrarosa® is a vaginal ovule. You place it in your vagina with the provided applicator (A), or with your fingers (B). Do not use any other applicator.
- Empty your bladder and wash your hands before handling the vaginal ovule and the applicator.
- Tear off 1 vaginal ovule along the perforations from the ovule strip.

A. Using the applicator



Step 1

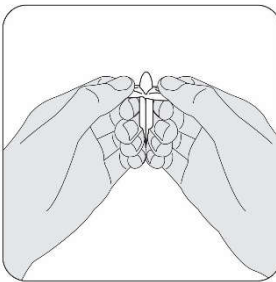
- Remove 1 applicator from the pack. It must be activated before use.
- To activate it pull back on the plunger until it stops.
- Place the applicator on a clean surface.



Step 5

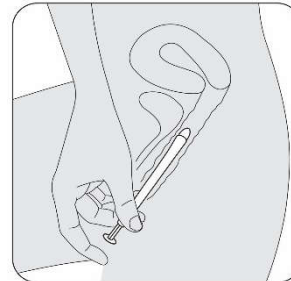
- To place the ovule, select the position that is most comfortable for you.

5a. Lying position

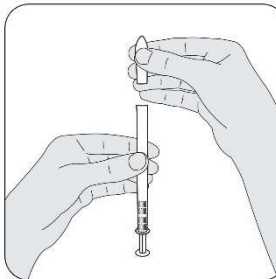


Step 2

- Keep the vaginal ovule between your fingers and slowly pull apart the plastic tabs.
- Carefully remove the ovule from the plastic wrap.
- If it falls on an unsanitary surface, replace it with a new one.

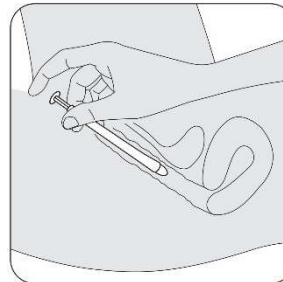


5b. Standing position



Step 3

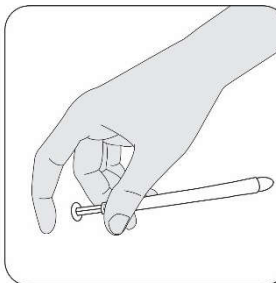
- Place the flat end of the ovule into the open end of the activated applicator as shown. You are now ready to place the ovule into your vagina.



Step 6

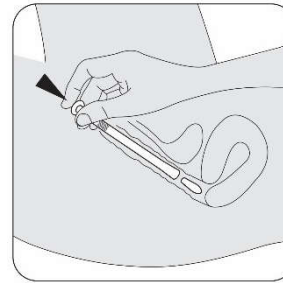
- Gently slide the ovule end of the applicator into your vagina. Place it as far as it will comfortably go.

Do NOT use force.



Step 4

- Hold the applicator between your thumb and middle finger.
- Leave your index (pointer) finger free. You will use it to press the plunger after the applicator is placed into your vagina.



Step 7

- Press the applicator plunger with your index (pointer) finger. This will release the ovule into your vagina.
- Remove the applicator.
- Wash the applicator:
 - a. take the plunger out of the body of the applicator;
 - b. rinse the 2 pieces for 30 seconds under running water;
 - c. wipe with a paper towel or something similar;
 - d. put the applicator back together.
- Throw the applicator away after using it for one week.

B. Using fingers

Unwrap the ovule as shown above in Step 2. Place the ovule into your vagina with your fingers as far as it can comfortably go. **Do NOT use force.**

Usual Dose:

One vaginal ovule once a day at bedtime.

Dosage Adjustment:

See your healthcare professional every 6 months – or more often, if needed.

Follow your healthcare professional's recommendations.

Your healthcare professional will see if you need to keep using Intrarosa®.

Overdose:

If you think you, or a person you are caring for, have taken too much Intrarosa®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use a vaginal ovule, use one as soon as you remember. However, if the next dose is due in less than 8 hours, skip the missed dose.

Do not use two vaginal ovules to make up for a forgotten dose.

What are possible side effects from using Intrarosa®?

These are not all the possible side effects you may have when taking Intrarosa®. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effect is vaginal discharge. The leakage can be due to:

- the melting of the hard fat ingredient.
- the increased vaginal secretions.

A change in your breast exam or Pap test results can occur while you take Intrarosa®. Your healthcare professional will decide when to perform breast exams and Pap tests and will interpret the results.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax;

or

- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2°C to 30°C in original package to protect from light.

Keep out of the reach and sight of children.

If you want more information about Intrarosa®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (www.intrarosa.ca), or by calling 1-844-587-4623.

This leaflet was prepared by Cosette Pharmaceuticals, Inc.

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