

Your Dream. Your Choice.

The **#1 prescribed vaginal progesterone**
to help your dreams of pregnancy come true



Using CRINONE®: Follow the steps below to deliver progesterone to help your body achieve and maintain a pregnancy.



1.

Remove the applicator and the plunger from the sealed wrapper. Don't remove the twist-off cap from the applicator yet.

Hold the applicator between your thumb and forefinger and push the plunger into the applicator until the plunger snaps into place.

You should see about 1 inch of the plunger outside of the applicator.



2.

Remove the cap from the tip of the applicator by twisting it counterclockwise.

Be sure not to push the plunger while you're removing the cap as it can cause some gel to come out.



3.

Find the position that's most comfortable for you: lying down on your back with your knees bent or sitting on the edge of your bed or in a chair with your knees apart.

When you're comfortable, gently insert the rounded tip of the applicator into your vagina.



4.

While the applicator is in your vagina, push the plunger to release the gel.

Remove the applicator and throw it away in your regular household trash. Don't worry if you still see a small amount of gel in the applicator. That's normal — you'll still get the right dose of medicine.

The improved applicator is designed for your comfort and ease of use.

The improved slim, rounded vaginal applicator is similar to a tampon applicator. Just one dose each morning makes it easy for you to get up, use your CRINONE and get on with your day.

Some things to know:

- CRINONE is made of a unique gel that coats and adheres to the vaginal walls after application, allowing it to be absorbed through the vaginal tissue and delivered directly to the uterus. No other progesterone offers this distinct delivery method.
- Spotting and/or bleeding is possible with CRINONE.
- Small, white globules may appear as a vaginal discharge possibly due to gel accumulation, even several days after usage. It is not unusual.

If you have any concerns, be sure to speak to your doctor or nurse.

Indication and Usage

CRINONE 8% (progesterone gel) is indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency.

Important Safety Information

The most common side effects of CRINONE 8% (progesterone gel) include breast enlargement, constipation, drowsiness, nausea, headache, and pain in the pubic area. You should not use CRINONE 8% if you have any disorders involving blockage of your blood vessels, or a history of these disorders, miscarriages, vaginal bleeding that hasn't been diagnosed, liver problems or disease, or known or possible cancer of the breast or genital organs. You should discontinue use of CRINONE 8% if any symptoms occur that signal a blockage of your blood vessels. There is no evidence that CRINONE 8% will work in preventing miscarriage. Your doctor should examine your breasts and pelvic organs, as well as perform a Pap smear prior to prescribing CRINONE 8%. If you have vaginal bleeding during treatment with CRINONE 8%, your doctor should look for the cause. If you have conditions that cause fluid retention, a history of depression, or diabetes, your doctor should provide special attention to your care while you are using CRINONE 8%.

Please see the Patient Information.

Reference: CRINONE [package insert]. Parsippany, NJ: Watson Pharma, Inc; 2013.



PATIENT INFORMATION

Crinone® 4% and Crinone® 8% (progesterone gel)

For Vaginal Use Only

Please read this information carefully before you start to use Crinone and each time your prescription is renewed, in case anything has changed. This leaflet does not take the place of discussions with your doctor. If you still have any questions, ask your doctor or healthcare provider.

What is Crinone?

Crinone is medicine that contains the female hormone called progesterone.

What is Crinone used for?

- Crinone 4% and Crinone 8% are used to treat the absence of a menstrual period in a woman who has previously had a menstrual period. Progesterone is one of the hormones that allows women to have regular menstrual periods. When you do not produce enough progesterone, menstrual irregularities can occur. Crinone may be prescribed to increase your progesterone.
- Crinone 8% is also used as part of a program for women who are undergoing fertility treatments to get pregnant. Progesterone is one of the hormones that helps to prepare the lining of your uterus so that it is ready to receive and nourish a fertilized egg and to continue a pregnancy. If you are undergoing ART treatment and your doctor has determined your body does not produce enough progesterone on its own, Crinone may be prescribed to increase your progesterone.
- If pregnancy occurs, Crinone may be supplemented for 10 to 12 weeks until production of progesterone by the placenta is adequate.

Who should not use Crinone?

- Do not start using Crinone if you:
- Are allergic to progesterone, progesterone-like drugs, or any of the inactive ingredients in the gel (ask a pharmacist if you are not sure about the inactive ingredients in Crinone).
 - Have unusual vaginal bleeding which has not been evaluated by a doctor.
 - Have or have had a liver disease.
 - Have or have had cancer of the breast or genital organs.
 - Have had a miscarriage and your physician suspects some tissue is still in the uterus.
 - Have or have had blood clots in the legs, lungs, eyes, or elsewhere.

What are the possible side effects of Crinone?

Serious side effects include:

- Blood clots. Postgestational drug products may increase your chance of having blood clots in your blood vessels. Blood clots can cause:
 - stroke
 - blood vessel problems (thrombophlebitis)
 - loss of your arm or leg
 - blood clot in your lungs (pulmonary embolus)
 - heart attack
 - death
 - Birth defects. Abdominal wall defect and cleft palate have been reported with Crinone use in early pregnancy. It is not known if these defects were caused by Crinone.
- Call your healthcare provider right away if you get any of the following warning signs or any other unusual symptoms that concern you:**
- Pains in the calves or chest, a sudden shortness of breath or coughing blood indicating possible clots in the legs, heart, or lungs.
 - Severe headache or vomiting, dizziness, faintness, or changes in vision or speech, weakness or numbness of an arm or leg indicating possible clots in the brain or eye.

Common side effects include:

- abdominal pain
 - perineal pain (the perineum is the area between the vagina and the rectum)
 - cramps
 - bloating
 - headache
 - fatigue
 - increased appetite
 - constipation
 - diarrhea
 - nausea
 - joint pain
 - depression
 - mood swings
 - sleep disorder
 - nervousness
 - decreased libido
 - breast enlargement
 - excessive urination at night
 - vaginal discharge
 - upper respiratory tract infection
- These are not all the possible side effects of Crinone. For more information, ask your healthcare provider or pharmacist for advice about side effects. **You may report side effects to FDA at 1-800-FDA-1088.**

How should I use Crinone?

Use as directed by your healthcare provider.

Read the instructions for Use included in this leaflet for information on the right way to use Crinone.

Additional information about Crinone

- You may see a small amount of white discharge that may look like a vaginal discharge. This discharge may be caused by gel that can remain in your vagina, even several days after use. Gel discharge from your vagina is normal, but if you are concerned, talk to your healthcare provider.
- If you miss a dose of Crinone, use it as soon as you remember.
- **Do not** use more Crinone than the dose prescribed by your doctor.
- Talk to your healthcare provider about whether to use other vaginal medicines when you are using Crinone.

General information about the safe and effective use of Crinone

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use Crinone for another condition. Your doctor has prescribed this drug for you and you alone. Do not give this drug to anyone else, even if they have the same condition.

Keep Crinone out of the reach of children

This leaflet provides the most important information about Crinone. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about Crinone that is written for health professionals.

You can get more information by calling the toll free number 1-888-776-4358 or visit www.crinoneusa.com.

What are the ingredients in Crinone?

Crinone contains either 45 mg (4% gel) or 90 mg (8% gel) of progesterone in a base containing glycerin, light mineral oil, polycarbophil, carbomer homopolymer Type B, hydrogenated palm oil glyceride, sorbic acid, purified water and may contain sodium hydroxide.

How should I store Crinone?

- Store Crinone at room temperature between 68°F to 77°F (20°C to 25°C).
- **Do not** use Crinone after the expiration date printed on the box.

Instructions for Use

Crinone 4% and Crinone 8% ("KRI-noan")
(Progesterone gel)

For Vaginal Use Only

You will need the following supplies: See Figure A

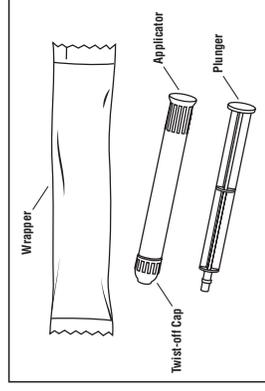


Figure A

Step 1. Remove the applicator from the sealed wrapper.

- Open the sealed wrapper and remove the applicator. Do not remove the twist-off cap at this time. **See Figure B**

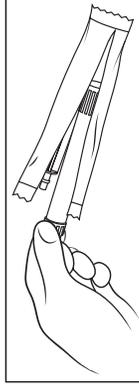


Figure B

Step 2. Insert the plunger into the open end of the applicator. See Figure C

- Hold the applicator on each side and push the plunger into the applicator until the plunger snaps into place.
- You will see about 1 inch of the plunger outside of the applicator.

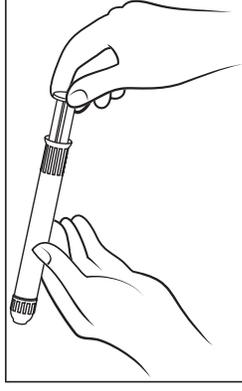


Figure C

Step 3. Remove the cap. See Figures D and E

- Remove the cap from the tip of the applicator by twisting it counterclockwise.
- Do not push the plunger while you are removing the cap. This could cause some gel to come out.

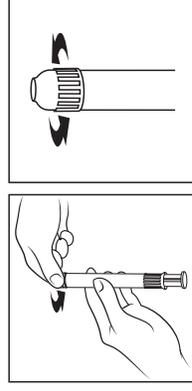


Figure D

Figure E

Step 4. Prepare to insert the applicator. See Figure F

- Choose the position that is most comfortable for you. For example, lying down on your back with your knees bent.

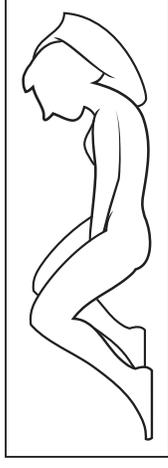


Figure F

Step 5. Insert the applicator. See Figure G

- After you are in a comfortable position, gently insert the rounded tip of the applicator into your vagina.

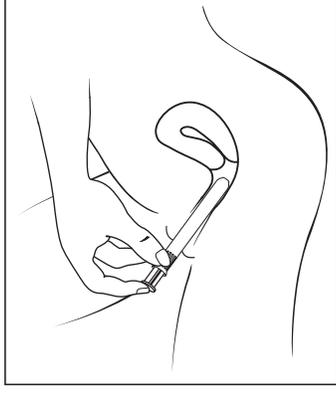


Figure G

Step 6. Push the plunger. See Figure H

- While the applicator is inserted in your vagina, push the plunger to release the gel into your vagina.

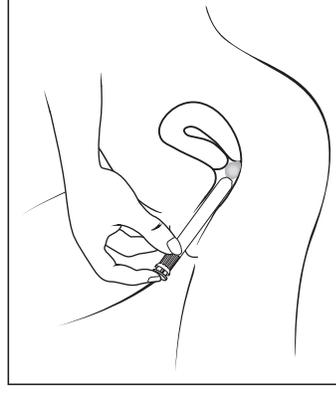


Figure H

Step 7. Remove the applicator from your vagina and throw it away in your household trash.

- It is normal for a small amount of gel to be left in the applicator. You will still get the right dose of medicine.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Rx only

For all medical inquiries contact:

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