

Crinone[®]

progesterone gel 8%

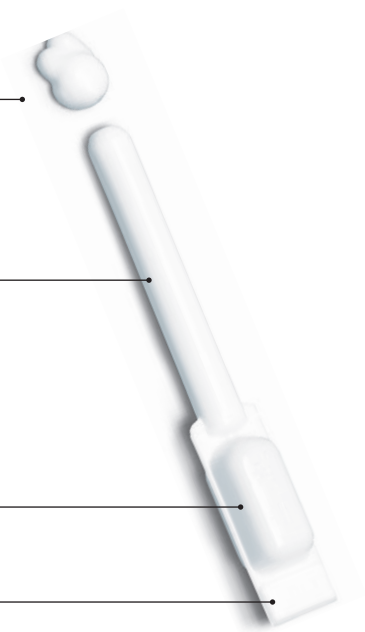
Administration and storage instructions

CRINONE[®]
Progesterone Gel

Thin End

Thick End

Flat Section



ADMINISTRATION

REVIEW THESE STEPS BEFORE YOU ADMINISTER CRINONE

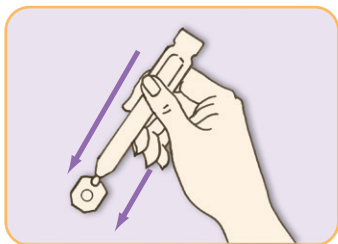
Before you begin:

- Remove the applicator from the sealed wrapper.
- DO NOT remove the twist-off tab at this time.



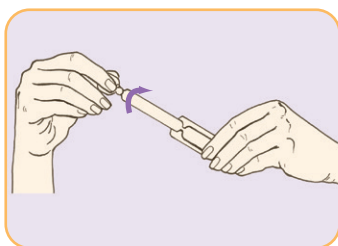
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Step 1



Grip the applicator by the thick end. Shake it in a downwards motion like a thermometer to ensure that the contents are at the thin end.

Step 2



Twist off the tab and discard.

Step 3



The applicator may be inserted into the vagina while you are in a sitting position or when lying on your back with your knees bent. Gently insert the thin end well into the vagina.

Step 4



Press the thick end of the applicator firmly to deposit gel. Remove the applicator and discard it into a waste container.

Frequently Asked Questions

What is CRINONE?

CRINONE's active ingredient is progesterone. Each dose of the gel contains 90 mg / dose (8% gel) progesterone.

CRINONE is used for luteal phase support in induced cycles such as *In Vitro* Fertilization (IVF) cycles (including oocyte donation recipients with or without functional ovaries).

How to use CRINONE?

One application of CRINONE 8% (90 mg of progesterone) every day, starting the day of the transfer. In some cases, the dose can be increased to two applications of CRINONE 8% daily. If pregnancy occurs, treatment should be continued for up to 10 to 12 weeks.

CRINONE is to be applied directly from the specially designed applicator into the vagina. CRINONE coats the vaginal mucosa to provide long-lasting release of progesterone.

Is it normal to see gel left in the applicator?

Each applicator contains a slightly larger amount of gel than actually released, as the rest of the product tends to stick to the inside of the applicator. It is therefore quite normal for a little gel to be left inside. Each applicator is intended for single use only. Any content of gel remaining in the applicator after use must be discarded.

I'm getting some discharge. Is my CRINONE falling out?

Typically the gel stays attached to the vaginal walls as the medicine absorbs. Do not be concerned if small globules appear as a discharge after several days of usage. It is common, not harmful, to have some gel residue build-up. Gel accumulation may be less likely to occur if the gel is applied in the morning because activities like walking may help spread the gel on the vaginal walls.

Therefore, it is not necessary to remain lying down following administration of CRINONE. If gel accumulation becomes bothersome, talk to your doctor.

How should I store my CRINONE?

CRINONE gel should be stored at room temperature (15-25°C) and not exposed to extreme heat or cold. As with all medicines, the gel applicators should be kept in a safe place where children cannot reach them.

Who should not use CRINONE?

CRINONE should not be used in individuals with any of the following conditions:

- Undiagnosed vaginal bleeding
- Liver dysfunction or disease
- Known or suspected malignancy of the breast or genital organs
- Known or suspected progesterone dependent neoplasia
- Known sensitivity to CRINONE (progesterone or any of the other ingredients)
- Missed abortion
- Thrombophlebitis, thromboembolic disorders, cerebral apoplexy or patients with a history of these conditions
- Acute porphyria

What are the side effects?

The following side effects have been reported with CRINONE: cramps, breast pain, headache, pain, bloating, nausea, vaginal discharge, somnolence, intermenstrual bleeding, vaginal irritation and application site reactions. There have been occasional reports of drowsiness associated with the use of CRINONE. Therefore TAKE CARE if you intend to drive or operate machinery. If you experience these effects and they become troublesome, please consult your doctor.

What happens if I forget to take my CRINONE or if I overdosed?

Missed dose: If you forget to use CRINONE on a normal dosage day then use it the following day and then continue as before. Do not administer double doses to make up for a forgotten single dose.

Overdose: Overdosage is not anticipated because each dose is applied through an individual disposable applicator. However, if it occurs, the treatment with CRINONE 8% should be discontinued.

What are the other important points to remember?

- This medication has been prescribed only for your current medical condition. Do not use it for other medical conditions.
- Do not use CRINONE gel after the expiry date printed on the label.
- Do not allow people to use your medications and do not use medications meant for other people.
- CRINONE should not be administered simultaneously with other intravaginal therapies. If other local intravaginal therapy is to be used simultaneously, there should be at least a 6-hour period before or after CRINONE administration. Tell any doctor treating you what medications you are taking. Always carry a medical information card stating which medications you are using. This can be very important in case you are involved in an accident. Make sure that other people you live with or who look after you read this information.
- CRINONE should not be used during lactation
- CRINONE must not be used in children
- **For additional information, please refer to the package insert that came with your medication.**

You are not alone.

Where can you get help and find more information?


momentum

The *MOMENTUM* patient services program is a free and confidential service that offers customized patient support, including injection assistance, to individuals using EMD Serono fertility products.

 **fertility.mymomentum.ca**

Our comprehensive patient website is designed to provide:

- Technical support including downloadable injection guides and videos
- Frequently asked questions on EMD Serono products

 **1-800-387-8479**

- Our *MOMENTUM* toll-free helpline is available 24 hours a day, 7 days a week
- Regular hours are 8:00 a.m. to 8:00 p.m. (Eastern Time), Monday to Friday
- An after-hour pager service is available for urgent inquiries that cannot wait until the following business day. Simply leave your name, reason for calling, and your phone number, and a registered nurse will return your call in a timely manner

***MOMENTUM* is available in over 250 languages through the assistance of certified translators.**

MOMENTUM will not comment on individual diagnosis or treatment questions, laboratory results or products not manufactured by EMD Serono. You should discuss those with your healthcare provider. *MOMENTUM* is a source of educational support sponsored by EMD Serono, Canada, and is not intended to replace discussions with your healthcare provider.


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