#### What are the other important points to remember?

- 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.
- 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.

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

Call MOMENTUM toll-free at 1-800-387-8479 between the hours of 8:00 a.m. and 8:00 p.m. (Eastern Time), Monday to Friday. **MOMENTUM** is available 24 hours a day, 7 days a week for urgent inquiries that cannot wait until the following business day. For after hours calls, 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 is also available online at fertility.mymomentum.ca.

For more information on Crinone® please refer to the package insert that came with your medication.

**MOMENTUM** will not comment on individual diagnosis, treatment questions, or laboratory results. You should discuss those with your healthcare provider.

**MOMENTUM** is a source of educational support sponsored by EMD Serono, Canada



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1-800-387-8479

MOMENTUM is a complimentary and confidential phone service which offers support for patients who are prescribed EMD Serano fertility products MOMENTUM is also available online at fertility.mymomentum.ca



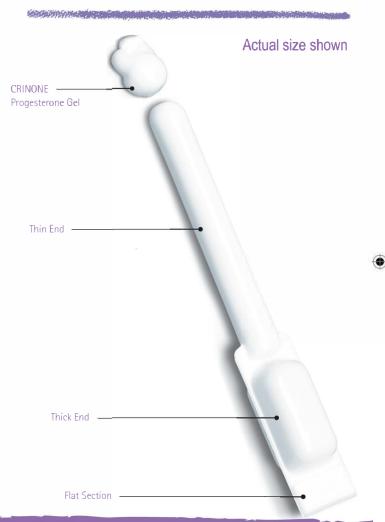


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Crinone® is a registered trademark of Columbia Laboratories



#### ADMINISTRATION AND STORAGE INSTRUCTIONS



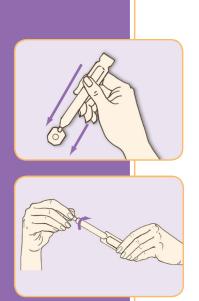
## Administration REVIEW THESE STEPS BEFORE YOU ADMINISTER CRINONE

## Before you begin

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







### 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 as far up as you comfortably can 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.

#### What is CRINONE used for?

CRINONE (Progesterone gel) 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).

#### Who should not use CRINONE?

Tell your doctor or pharmacist if: you are allergic to any of the ingredients found in Crinone, you have abnormal vaginal bleeding, you have porphyria (congenital or acquired disorder of the biosynthesis of the red blood stain), you have malignant disease of the breast or genital organs, or if such a disease is suspected, you have an acute blood clot including

inflammation of superficial veins (thrombophlebitis), a vascular occlusion (thormboembolic disorder), or a cerebral apoplexy, or if you have had such disease before, you are pregnant with a dead fetus (missed abortion), you are breast feeding, you have liver disease, epilepsy, heart or kidney problems, or are using any other vaginal product.

#### 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.

### How should I take CRINONE?

Insert one application of CRINONE every day, starting the day of the embryo transfer (or as directed by your physician), directly from the specially designed applicator into the vagina.

In some cases, your doctor may increase the dose to two application of CRINONE daily. If pregnancy occurs, treatment with CRINONE should be continued for up to 10 to 12 weeks of pregnancy.

# 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. In fact, each applicator contains 1.45g of vaginal gel to deliver exactly 1.125g. It is therefore quite normal for a little gel to be left inside the applicator, and 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. That said, it is common, and not harmful, to have some gel residue build-up. Do not be concerned if small globules appear as a discharge after several days of usage. If gel accumulation becomes bothersome, talk to your doctor.

#### Is it normal to have gel build up?

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 you have concerns over gel accumulation, talk to your doctor or call MOMENTUM at 1-800-387-8479.

#### How do I store Crinone?

CRINONE gel should be stored at room temperature (15-25°C) and not exposed to extreme heat or cold.