PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

CRINONE®
Progesterone vaginal gel, 8%

Read this carefully before you start taking **CRINONE®** 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 **CRINONE®**

What is CRINONE® used for?

CRINONE® is used in fertility treatments such as *In Vitro Fertilization* (IVF). It is used to support part of the menstrual cycle called the luteal phase. It may be used in women who use their own egg or who receive an egg donation.

How does CRINONE® work?

CRINONE® coats the lining of the vagina. This creates long-lasting release of progesterone. This will help prepare the lining of the uterus for pregnancy and help to maintain a pregnancy.

What are the ingredients in CRINONE®?

Medicinal ingredients: Micronized progesterone.
Non-medicinal ingredients: carbomer 974P, glycerin, hydrogenated palm oil glyceride, light liquid paraffin, polycarbophil, purified water, sodium hydroxide, sorbic acid.

CRINONE® comes in the following dosage forms:

Gel 8% : 90 mg

CRINONE® is packaged in a disposable applicator that is used in the vagina. The applicator has a twist-off top. It contains 1.45g of gel and delivers 1.125g of gel.

Do not use CRINONE® if:

- you are allergic to progesterone or to any of the other ingredients in CRINONE®;
- you have abnormal vaginal bleeding;
- you have porphyria. This is a group of disorders that affect the production of hemoglobin in the blood; You may have been born with porphyria or it may have developed during your lifetime.
- you have or think you have breast cancer or a cancer of the genitals;
- you have or think you have a cancer that is considered 'progesterone-dependent';
- you have, or have a history of:
  - a thrombophlebitis. This is when blood clots form due to inflammation and block veins. It typically happens in the veins of the leg.
  - a thromboembolic disorder. This is when you have problems with blood clots
  - a stroke
- you are pregnant but your baby has died in your womb;
- you are breast feeding;

- you have liver problems or liver disease;
- you are using any other products in your vagina.

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

- have a blood clotting condition or are at increased risk for blood clots. This might include conditions like: thrombophlebitis, cerebrovascular disorders, pulmonary embolism, and retinal thrombosis.
- develop jaundice, which is when your skin and the whites of your eyes become yellow.
- experience changes in the levels of liver enzymes in your blood.
- have any of:
  - depression
  - epilepsy
  - migraines
  - asthma
  - heart problems
  - kidney problems
  - diabetes

Other warnings you should know about:

Before starting treatment, your healthcare professional will do a physical examination. They will check the organs in your pelvis, your breasts and will do a Pap smear.

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 CRINONE®:

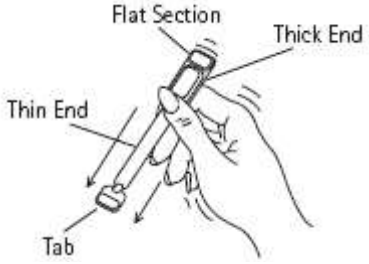
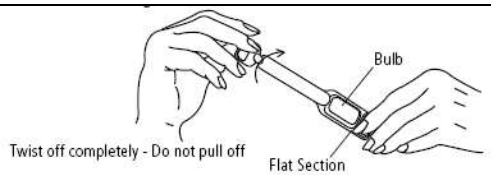
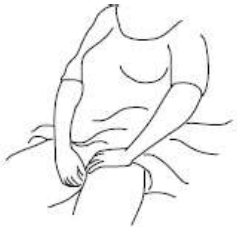
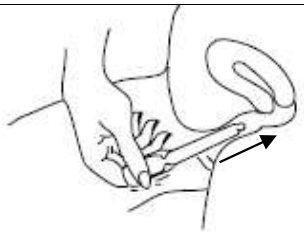
Although no drug interaction with other drugs have been reported, CRINONE® should not be used at the same time as other vaginal products. If you need to use other products that go into vagina, use CRINONE® either 6 hours before or 6 hours after using these other medicines.

How to use CRINONE®:

- Use the specially designed applicator to apply CRINONE® into the vagina. To apply CRINONE®, follow the steps below under **Instructions for Use**.
- Each applicator contains a little more gel than is actually released. It is normal for some gel to be left inside the applicator after you have applied CRINONE®.
- Discard the applicator after you have used it. Only use each applicator once.
- Gel build-up (accumulation):
  - Usually CRINONE® stays attached to the wall of the vagina after it is applied.
  - Do not be concerned if you notice globules in discharge from the vagina after several days of using CRINONE®.
  - Sometimes the gel will build up in the vagina. This is common and not harmful. It is less likely for this to happen if you apply the gel in the morning. This is because activities like walking may help to spread the gel onto the walls of the vagina. You do not have to stay lying down once you have applied the gel.
  - If build-up of CRINONE® happens to you and it is bothersome, contact your healthcare professional.

Instructions For Use:

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

1. Grip the applicator by the thick end. Shake down like a thermometer to ensure that the contents are at the thin end.	
2. Twist-off the tab and discard.	
3. Insert the applicator 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.	
4. Press the thick end of the applicator firmly to deposit gel. Remove the applicator and discard into a waste container.	

Usual dose:

- One application every day, starting the day of the embryo transfer.
- Your healthcare professional may increase your dose to 2 applications per day.
- If you get pregnant, continue to use CRINONE® for up to 10 to 12 weeks.

Overdose:

If you think you, or a person you are caring for, have used too much CRINONE®, 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 CRINONE®, skip the missed dose and continue with your regular schedule. Do not administer 2 doses at the same time to make up for a forgotten dose.

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

- breast tenderness or breast pain
- spotting (bleeding between periods)
- irritation of the vagina
- reactions at the site of the application
- genital candidiasis (yeast infection on organs of reproduction)
- urinary tract infection
- headache, migraine
- dizziness
- drowsiness or sleepiness
- abdominal pain
- constipation
- diarrhea
- nausea
- vomiting
- abnormally swollen abdomen
- depression
- memory loss
- aggressive behaviour
- nervousness
- accidental loss of urine
- bladder infection
- decreased libido
- painful intercourse
- itchy genitals
- dryness of the vulva or vagina
- vaginal discharge
- muscle cramps
- joint pain, pain
- fatigue
- intense itching
- rash, hives, skin disorder

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Hypersensitivity (allergic reaction): fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy watery eyes			✓

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/adverse-reaction-reporting.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 CRINONE® at room temperature (15-25°C). Do not expose it to extreme heat or cold.

Keep out of sight and reach of children.

Do not use CRINONE® gel after the expiry date, which is printed on the label.

If you want more information about CRINONE®:

- 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; http://www.emdserono.ca, or by calling 1-800-387-8479.

This leaflet was prepared by EMD Serono, A Division of EMD Inc., Canada.

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