



Package Leaflet: Information for the user

Crinone® 8% w/w Vaginal Gel

Progesterone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Crinone is and what it is used for
2. What you need to know before you use Crinone
3. How to use Crinone
4. Possible side effects
5. How to store Crinone
6. Contents of the pack and other information

1. What Crinone is and what it is used for

The full name of your medicine is Crinone 8% w/w vaginal gel. In this leaflet the shorter name Crinone is used. Crinone contains a hormone called progesterone. When the gel is inserted into your vagina, the progesterone is slowly released into your bloodstream throughout the day.

Crinone is used to give you extra progesterone in the treatment of infertility due to incorrect levels of progesterone during the menstrual cycle or when you are having an assisted fertility procedure. This is to help you get pregnant. You may also be asked to continue using Crinone to support your new pregnancy.

2. What you need to know before you use Crinone

Do not use Crinone:

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).
- if you have unexplained vaginal bleeding
- if you have porphyria (an inability to break down certain substances (porphyrins) in your blood that is passed down in families)
- if you have or think you might have cancer in your breasts or genital organs
- if you have ever had a blood clot due to swollen veins (thrombophlebitis), a blocked blood vessel (thromboembolic disorder) or a stroke
- if you are pregnant but your baby has died inside of you (missed abortion).

Do not use Crinone if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before using this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before using Crinone if any of the following apply to you. They may want to monitor you more closely during treatment:

- if you have liver or kidney problems
- if you have heart problems or diabetes
- if you have asthma
- if you have epilepsy or often get migraines
- if you have ever had depression.

Tell your doctor if you get any unexpected bleeding so that they can investigate the cause of this.

Children and adolescents

Crinone is not for use in children or adolescents.

Tests and check ups

Check ups are required before you use this medicine and every so often when you are using it. In particular:

- Before using this medicine, your doctor will need to do a smear test and check your breasts and pelvic area.
- During your treatment, your doctor will check for any problems with your womb such as the lining getting thicker (endometrial hyperplasia). They will also check for any signs of blood clots in your blood vessels.

Other medicines and Crinone

Do not use Crinone at the same time as any other medicines that are inserted into your vagina.

Tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

- Crinone is not normally used during pregnancy. However, if you used Crinone to help you get pregnant, you may be asked to continue using it to support your new pregnancy.
- The use of Crinone during breast-feeding is not recommended.

Driving and using machines

You may feel very tired while using Crinone. If this happens, do not drive or use machines. Drinking alcohol can make this tiredness worse.

Crinone contains sorbic acid

Crinone contains sorbic acid. This may cause local skin reactions such as contact dermatitis. These skin reactions might also occur on your partner's penis if you have sex while using Crinone. This may be prevented by using condoms.

3. How to use Crinone

Always use Crinone exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose

Insert the contents of one applicator of Crinone into your vagina each day, starting after your doctor tells you that you have ovulated, or on the 18th-21st day of your menstrual cycle. (The first day of your menstrual cycle is the day your period starts.)

When used during in-vitro fertilisation, from the day of the embryo transfer, insert the contents of one applicator of Crinone into your vagina each day, preferably in the morning. Once tests confirm that you are pregnant, you may be asked to keep using Crinone to support your new pregnancy – for a total of 30 days.

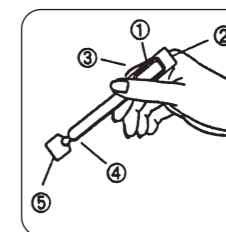
The applicator is designed in such a way that an exact amount of gel (1.125 g, containing 90 mg progesterone) is delivered. It is expected that a small amount of gel will be left in the applicator. This can be thrown away as you will have received all of the medicine that you need.

How to use

This medicine is only for use in your vagina using the pre-filled applicator supplied in the pack.

Before using the applicator, please read all of the instructions below.

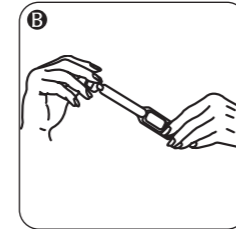
What your applicator looks like



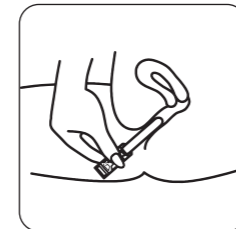
1. air tank
2. flat part of the thick end
3. thick end
4. thin end
5. cap

Getting your applicator ready

Grip the applicator by the thick end between your thumb and index finger. Face the thin end of the applicator down to the ground and shake the applicator down to move all the gel inside to the thin end.

Opening your applicator

Grip the applicator by the flat part of the thick end. Twist off and remove the cap from the opposite thin end. To stop the gel from flowing out before use, do not press the air tank at the thick end at this stage.

Inserting your applicator

Lean back or lie down with your knees bent and spread apart. Carefully insert the applicator well into your vagina, until your hand touches your body.

Press the air tank at the thick end of the applicator firmly to deliver the gel from the applicator into your vagina.

After using your applicator

Throw away the applicator, including the small amount of gel that is left inside. Use each applicator only once.

Crinone gel can stay in your vagina for several days. You may get a beige to brownish clumpy or cloudy white discharge during this time. This is nothing to worry about.

If you use more Crinone than you should

You are unlikely to use too much of this medicine as each applicator contains the right amount.

If you forget to use Crinone

Do not use a double dose to make up for a forgotten dose. If you forget to use Crinone on one day, please continue as usual with a single dose on the following day. If you have any further questions on the use of this medicine ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

If you get an allergic reaction stop taking Crinone and see a doctor straight away. You may get for example an itchy skin rash. It is not known how likely this side effect is.

Other side effects

Common (may affect up to 1 in 10 people):

- headache
- feeling very tired
- stomach or gut (gastro-intestinal) cramps
- breast tenderness.

Uncommon (may affect up to 1 in 100 people) to very rare (may affect up to 1 in 10,000 people):

- bleeding between periods (spotting)
- irritation or other mild reactions in or around your vagina.

Please note

Crinone gel can stay in your vagina for several days.

You may get a beige to brownish clumpy or cloudy white discharge during this time. This discharge can cause irritation, pain or swelling of the vagina but this is nothing to worry about.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Crinone

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the cartons and the wrapper after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Use each applicator only once. Any gel left in the applicator must be thrown away.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and further information**What Crinone contains**

- The active substance is progesterone. From each applicator 1.125 g vaginal gel, containing 90 mg progesterone, is delivered into the vagina.
- The other ingredients are sorbic acid, glycerine, light liquid paraffin, hydrogenated palm oil glycerides, carbomer 974P, polycarbophil, sodium hydroxide and purified water.

What Crinone looks like and contents of the pack

Crinone is a smooth white to off-white gel. It is filled in single-use, one-piece, white polyethylene vaginal applicators with twist-off caps, each sealed in a paper /aluminium / ionomer resin foil wrapper.

Crinone is supplied in packs of 6 or 15 single-use applicators. Not all pack sizes may be marketed.

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