

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Crinone 8% 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
- This medicine has been prescribed for you. 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

Crinone vaginal gel contains progesterone which belongs to the group of female hormones. Crinone vaginal gel is intended to be used as a complement in the treatment of infertility.

2. What you need to know before you use Crinone

Do not use Crinone

- if you are allergic to progesterone or to any of the other ingredients of this medicine (listed in section 6)
- if you have unexplained bleedings from the vagina
- if you have acute porphyria (an inherited disorder of metabolism)
- if you have breast cancer or cancer in the genitals
- if you have or have a history of any embolus disease, e.g. stroke

Warnings and precautions

- if you have irregular vaginal bleeding
- if you have hepatic impairment

Other medicines and Crinone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You should not use Crinone vaginal gel concurrently with other vaginal preparations.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Crinone vaginal gel can be used during the first trimester (the first 3 months) of pregnancy.

Breast-feeding

Crinone vaginal gel should not be used when you are breast-feeding.

Driving and using machines

Crinone has no known influence on the ability to drive and use machines.

Crinone contains sorbic acid

Crinone contains the preservative sorbic acid. This may cause local skin reactions such as contact dermatitis.

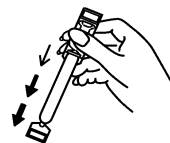
3. How to use Crinone

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

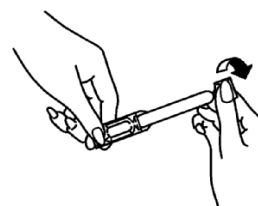
Instructions for use

Crinone vaginal gel is applied directly into the vagina with the specially designed applicator. Remove the applicator from its package. **OBSERVE:** Do not remove the twist-off cap at this point.

1. Grip the applicator firmly at the thick end. Shake the applicator in order to ensure that the contents are in the thin end of the applicator.



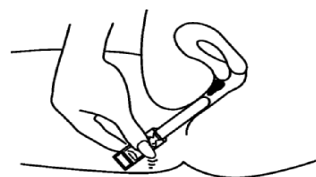
2. Remove the cap and discard it.



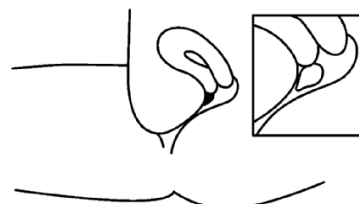
3. You can insert the applicator while sitting or lying down at your back with your knees bent. Insert the thin end of the applicator carefully and completely into the vagina.



4. Press the thick end of the applicator firmly in order to get the gel out of the applicator. Remove the applicator and discard it.



5. Crinone covers the vaginal mucosa and provides a slow release of progesterone.



If you use more Crinone than you should

If you have taken more medicine than you should or if for example a child has taken the medicine by mistake, contact your doctor or a hospital or the National Poison information Centre for assessment of the risk and advice.

If you forget to use Crinone

If you forget to use Crinone you can begin to use it again on the next day and continue to do as your doctor has prescribed. Do not take a double dose to make up for a forgotten dose.

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.

Common adverse reactions (may affect up to 1 in 10 people): Vaginal discharge, breast tenderness, headache and somnolence.

Adverse reactions with frequency not known (cannot be estimated from the available data): Spotting, irritation at the application site or hypersensitivity reactions usually in the form of skin rash.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). 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 store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 other information**What Crinone contains**

- The active ingredient of Crinone is progesterone. Each dose of the gel contains 90 mg progesterone.
- Other ingredients: glycerol, light liquid paraffin, hydrogenated palm oil glycerides, carbomer, polycarbophil, sorbic acid (E 200, preservative), sodium hydroxide, purified water.

What Crinone looks like and contents of the pack

A single use white polyethylene applicator, with a top that can be twisted-off. Each applicator contains 1.45 g gel and delivers 1.125 g gel. Each applicator is wrapped up and sealed in a paper / aluminium / polyethylene foil overwrap.

The applicators are packed in a paper box with 6 or 15 applicators of Crinone 8% vaginal gel.

Marketing Authorization Holder

[To be completed nationally]

Manufacturer

Catalent France Beinheim SA
74 Rue Principale Beinheim 67930
France

This medicine is authorised in the Member States of the European Economic Area under the following names:

Iceland: CRINONE 8 %
Sweden: CRINONE 8 %

This leaflet was last revised in: 2023-12-11

[To be completed nationally]