

Package leaflet: Information for the user

Crinone® 8% w/w progesterone 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 or nurse. 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
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1 What Crinone is and what it is used for

Crinone® 8% w/w Progesterone Vaginal Gel contains progesterone and is used for the treatment of infertility due to a deficiency of the female hormone progesterone during the menstrual cycle.

During the menstrual cycle, an egg develops in the ovary during the first 14 days. This is called the follicular phase of the menstrual cycle. Ovulation then occurs and leaves a corpus luteum in the ovary. This is called the luteal phase of the menstrual cycle. This corpus luteum produces progesterone for 12-16 days which helps to thicken and maintain the lining of the uterus (womb) ready for a fertilised egg. If fertilisation of the egg does not occur, the progesterone level falls and the lining of the uterus is shed (menstruation). If the egg is fertilised and the embryo implants in the lining of the uterus, the corpus luteum continues to produce progesterone to support the pregnancy until the embryo's placenta takes over at 10 weeks into the pregnancy. In some women the progesterone produced in the luteal phase is absent or insufficient to maintain the lining of the uterus and support early development of the embryo. Crinone® 8% w/w Progesterone Vaginal Gel provides the progesterone needed for this.

2 What you need to know before you use Crinone

Do not use Crinone:

- if you are allergic to active substance or any of the ingredients of this medicine (listed in section 6).
- if you have any unusual or heavy vaginal bleeding of unknown cause
- if you are breast-feeding
- if you suffer from porphyria (a hereditary metabolic disease)
- if you are using other vaginal preparations
- if you have known or suspected breast cancer or ovarian/uterine cancer
- if you have or have ever had a blood clot in a vein (thrombosis) or if there is a family history of thrombosis
- if you have ever had a stroke, or a bleed in the brain
- if you have a miscarriage, or the pregnancy has failed and a miscarriage has been confirmed

Warnings and precautions

Talk to your doctor or pharmacist before using Crinone

If you get bleeding between periods, make sure your doctor knows before you use Crinone.

Other medicines and Crinone

Tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, or might take any other medicines.

Pregnancy and breast-feeding

In the case of corpus luteum deficiency, Crinone can be used during the first month of pregnancy.

Do not use Crinone if you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

There have been occasional reports of drowsiness associated with the use of this product. Therefore TAKE CARE if you intend to drive or operate machinery.

Do not drive if you think that you might be affected.

Crinone contains sorbic acid

This medicine contains sorbic acid, which may cause local skin reactions (contact dermatitis).

3 How to use Crinone

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose

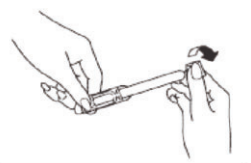
Apply this medicine once a day, starting after your doctor tells you that you have ovulated, or on the 18th- 21st day of your menstrual cycle. (The first day of your menstrual cycle is the day your period starts.)

The gel is to be applied directly from the specially designed sealed applicator into the vagina. 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.



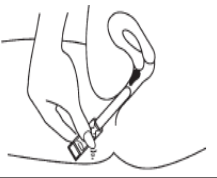
2. Twist off the tab and discard.



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



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



5. Your medication coats the vaginal mucosa to provide long-lasting release of progesterone.



If you forget to use Crinone

If you forget to use your medication on a normal dosage day, don't worry. Just use it the following day and then continue as before. Do not use a double dose to make up for a forgotten dose.

If you stop using Crinone

Talk to your doctor before you stop using Crinone and follow his advice.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

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

Frequency not known (cannot be estimated from the available data): There have also been reports of somnolence (drowsiness), breast tenderness, headache, intermenstrual bleeding (spotting), vaginal irritation and other mild application site reactions. Hypersensitivity reactions can sometimes happen and this can cause skin rashes on other parts of the body.

Reporting of 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 HPRAs Pharmacovigilance, website: www.hpra.ie. 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 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 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.

Each application of the gel contains a 90 mg dose of progesterone.

The gel also contains the following other ingredients: glycerol, light liquid paraffin, hydrogenated palm oil glycerides, carbomer 974P, sorbic acid, polycarbophil, sodium hydroxide and purified water.

What Crinone looks like and contents of the pack

White to off white gel contained in a white plastic applicator.

Crinone® 8% w/w Progesterone Vaginal Gel is available in packs containing 15 applicators.

Parallel Product Authorisation Holder:

Lexon Pharmaceuticals (Ireland) Limited, Block 3, Harcourt Centre, Harcourt Road, Dublin 2, Ireland.

Repackaged by:

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