

CRINONE[®] PROGESTERONE VAGINAL GEL

Progesterone (8% w/w)

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What Crinone is used for

Crinone is used to supplement progesterone in women who have luteal phase defect. Crinone is also used to supplement or replace your own natural progesterone in Assisted Reproductive Technology procedures (eg IVF). Your doctor may have prescribed Crinone for another purpose. Ask your doctor if you have any questions why Crinone has been prescribed for you.

How Crinone works

Crinone is a vaginal gel that contains natural progesterone. Progesterone is a hormone that is produced by the ovaries during the second half of the menstrual cycle. It is an essential hormone for preparing the uterus (womb) for pregnancy and on-going support of pregnancy. The lack of normal progesterone production by the ovaries in the second half of the menstrual cycle is called luteal phase defect. Women who have this defect may have difficulties in becoming pregnant and may have a higher risk of miscarriage.

Before you use Crinone

- When you must not use it

Do not use Crinone if:
You have ever had an allergic reaction to progesterone or to any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- rash (itching or hives) on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or
- troubled breathing or a tight feeling in your chest

Do not use Crinone if you have, or have had any of the following conditions:

- porphyria (rare genetic disease which affects mainly the skin or nervous system)
- abnormal vaginal bleeding that has not been diagnosed, or is due to a recent or current missed abortion or miscarriage
- Known or suspected progesterone-sensitive cancerous tumours

Do not use Crinone if you are breastfeeding.

Do not use Crinone after the expiry date printed on the label of the pre-filled applicator and the carton.

If you are taking this medicine after the expiry date has passed, it may not work.

Do not use Crinone if the packaging is torn or shows signs of tampering.

Do not use Crinone if the product appears to be discoloured, or the product does not look quite right.

Crinone is not for use in children.

Do not use Crinone to treat other complaints unless your doctor says it is safe.

Do not give this medicine to anyone else

- Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

See your doctor for a check-up before you start to use Crinone.

You must tell your doctor or

pharmacist if:

- you are breast feeding
- you are using other vaginal medications
- you suffer serious liver disease
- you or your family have or have ever had blood clots

If in doubt, consult your doctor or pharmacist before using Crinone.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or recently taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Crinone should not be used at the same time as other vaginal preparations.

How to use Crinone

Crinone is applied directly from the applicator deep into the vagina. The applicator is designed to deliver a pre-measured dose of progesterone gel. A small amount of gel will be left in the applicator after usage. Do not be concerned because you will still be receiving the required dose.

- How much to use

The amount of Crinone used depends on the condition being treated.

Your doctor may prescribe one applicator of Crinone once daily and will advise you when to start treatment.

- When to use it

Crinone should be used at the same time each day.

- How long to use it

You should use the treatment for as long as the doctor has advised you to use it. If pregnancy occurs, treatment may continue for up to 12 weeks or as directed by your doctor.

- If you forget to use it

If you forget a dose of Crinone, use it as soon as you remember, and then

continue on the same schedule as before.

- If you use too much (overdose)

If you use too much, immediately contact your doctor

While you are using Crinone

- Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

Tell any other doctors or pharmacists you visit that you are using Crinone. If you are about to start taking any new medicines, tell the doctor or pharmacist that you are using Crinone.

- Thing you must not do

Do not give this medicine to anyone else; it may harm them even if the reasons for using it seem to be the same as yours.

- Things to be careful of

Be careful driving or operating machinery until you know how Crinone affects you.

Some people feel drowsy and sleepy when using Crinone. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. The excipient sorbic acid may cause local skin reactions (e.g. contact dermatitis) or vaginal irritation.

Side effects

Crinone helps most women with a lack of progesterone, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following side effects when using Crinone:

Common side effects

- Headache
- Sleepiness
- Breast tenderness
- Vaginal irritation
- Itching or burning
- Other side effects may include vaginal spotting, mild application

site reactions and hypersensitivity reactions manifesting as skin rash.

This is not a complete list of all possible side effects.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Crinone

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Each applicator must be used once only. Use a new applicator for each treatment.

- Disposal

If your doctor tells you to stop taking Crinone, or the medicine have passed their expiry date ask your pharmacist how to dispose of medicines that no longer required.

Product description

- What it looks like

Crinone is a smooth, white to off-white gel with a fatty odour contained in a single use, one piece, white polyethylene applicator with a twist-off top, designed for intravaginal application.

Each one is wrapped up and sealed in a paper/aluminium/polyethylene foil overwrap.

- Pack size:

6 or 15 units of Crinone 8% w/w progesterone vaginal gel.

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient:

Progesterone

- Inactive ingredients:

Glycerin, Light Paraffin, Hydrogenated Palm Oil Glyceride, Carbopol 974P, Sorbic acid,

Polycarbophil Sodium hydroxide, Purified water.

- MAL Number:

MAL20020994ARZ

Manufacturer

Fleet Labs. Ltd., 94, Rickmansworth Road, Watford, Hertfordshire, WD 18 7JJ
UK

Product Registration Holder

Merck Sdn Bhd (178145-V)
Level 3, Menara Sunway Annexe,
Jalan Lagoon Timur
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Date of Revision

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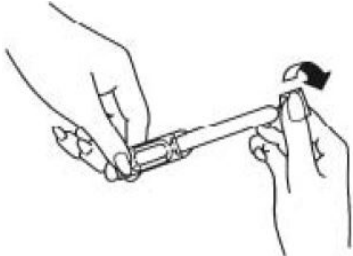
Method of Administration

Crinone is 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 firmly 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 while you are in a sitting position or when lying on your back with knees bent. Gently insert the thin end of applicator well into the vaginal.



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



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

