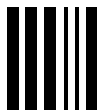


Merck Serono



Crinone® 8%

Progesterone vaginal gel



Please read this leaflet carefully before you start to use your medication. It contains a summary of the information available on your medication. If after reading this you have any questions ask your doctor or pharmacist.

ABOUT YOUR MEDICATION

The name of your medication is Crinone® 8% Progesterone Vaginal Gel. Its active ingredient is progesterone. Each application of the gel contains a 90 mg dose of progesterone.

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

Crinone® 8% Progesterone Vaginal Gel is available in packs containing 15 applicators. Your medication, containing progesterone, belongs to a group of medicines called female hormones.

WHAT YOUR MEDICATION IS FOR:

Crinone® 8% Progesterone Vaginal Gel is for the treatment of infertility due to incorrect levels of the female hormone progesterone during the menstrual cycle. It is also used during in-vitro fertilisation when infertility, in women who have normal ovulatory menstrual cycles, may be due to problems with the fallopian tubes or the womb. Sometimes there may be no apparent cause for the infertility.

BEFORE USING YOUR MEDICATION:

Please read the following questions. If your answer to any of them is YES, then tell your doctor or pharmacist before starting treatment:

- Are you allergic to any of the ingredients listed above?
- Do you have any unusual or heavy vaginal bleeding of unknown cause?

- Are you breast-feeding?
- Do you suffer from the hereditary metabolic disease porphyria?
- Are you using any other vaginal preparations?
- Have, or suspect you have, a tumor that is hormone sensitive?

The excipient sorbic acid has the potential to irritate the skin and cause inflammation (i.e. dermatitis)

Take special care with your medication:

- Talk to your doctor or pharmacist if you have severe liver disease.
- If you have a personal or family history of blood clots.
- 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.
- Stop treatment in case of miscarriage.
- If in doubt, consult your doctor or pharmacist before using this product.

HOW TO USE YOUR MEDICATION:

One application every 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, daily application of your medicine should be continued for 30 days if there is laboratory evidence of pregnancy.

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 your medication on a normal dosage day, don't worry. Just use it the following day and then continue as before.

AFTER USING YOUR MEDICATION

There have been occasional reports of drowsiness occurring during Crinone® 8% Progesterone Vaginal Gel treatment. If you are affected in this way do not drive or operate machinery.

There have also been reports of headache, breast tenderness, vaginal irritation, burning, slight bleeding or "spotting". There have also been rare reports of itching and hypersensitivity reactions which can cause skin rash.

If you experience these effects and they become troublesome, or you experience different side-effects, please consult your doctor or pharmacist.

STORAGE OF YOUR MEDICATION

This product should be stored at room temperature (below 30°C).

As with all medicines, the gel applicators should be kept in a safe place where children cannot reach them.

Do not use your medication after the expiry date which is printed on the label.

This leaflet was last approved in March 2013.

For further inquiries inside Egypt, Call 16935

Marketing Authorisation Holder

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This is a medicine

- A medicine is a product which affects your health and its consumption, contrary to instructions, is dangerous for you.
- Closely follow your doctor's prescription, the method of use and the instructions of the pharmacist who sold the product.
- Your doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the period of treatment prescribed without your doctor's permission.
- Do not repeat the same prescription without consulting your doctor.

Keep medicines out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists