ProFeme® 10

Cream containing 10% w/v (32 mg/mL) Progesterone B.P (Prog-4-ene-100-dione)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some of the common questions about PROFEME®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the possible risks of you using PROFEME® against the benefits it can have for you.

If you have any concerns about using PROFEME® talk to your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What PROFEME® is used for?

PROFEME® contains the active ingredient progesterone.

This form of progesterone is identical to the progesterone produced by the ovaries of women.

Progesterone plays an important role in the menstrual cycle, reproduction, hormone production, mood, fluid balance, metabolism, energy levels and well-being in women.

Where women suffer from a deficiency of progesterone one or more of these areas may be affected and PROFEME® provides progesterone to address this deficiency. The skin readily absorbs progesterone and PROFEME® is a clean, simple and effective means of getting progesterone into the body.

Prior to using PROFEME®

PROFEME® cream should not be used if you are allergic to progesterone, or any of the ingredients contained within PROFEME®. These are listed at the end of this leaflet. This product contains almond oil and macadamia nut oil. Do not use PROFEME if you have kidney disease, liver disease, unexplained abnormal vaginal bleeding or herpes during pregnancy (herpes gestationis). Check with your doctor or pharmacist if you are unsure about whether you have any of these conditions before using PROFEME®. If you are taking other medications check with your doctor or pharmacist before using PROFEME®. PROFEME® is best applied to the inner forearm or upper thigh. The area should be clean and dry.

No perfume, deodorant or moisturising creams or gels should be used on the area because this may interfere with PROFEME® from being absorbed.

Do not use PROFEME® after the expiry date which is printed on the base (crimp) of the tube.

Do not use PROFEME® if the foil seal at the top of the tube is damaged or broken.

PROFEME® is not indicated for use in children.

How to use PROFEME®

Your doctor or pharmacist will explain how to apply PROFEME®. Follow all directions exactly as they are explained. If you are unclear clarify with your doctor or pharmacist prior to use.

The dose of PROFEME® will be determined for you by your doctor. This dose will be specific to your condition and should not be varied unless directed to do so by your doctor.

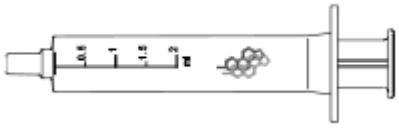
If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Opening the tube

To open the tube remove the cap and peel off the foil seal. Dispose of the foil seal and replace the cap firmly after using the cream.

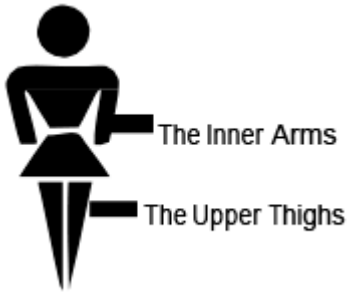
Measuring the correct dose of PROFEME® Cream

A measuring applicator (syringe style) in a sealed sleeve is enclosed in the PROFEME® box. The dose of PROFEME® is measured in millilitres. The applicator is marked with 0.5 mL graduations for dosing accuracy. Your doctor will have determined which dose is appropriate for you. To measure the correct dose of cream insert the tip of the applicator into the open nozzle of PROFEME® cream so that the nozzle and the shoulder of the applicator are in contact. GENTLY squeeze the base of the PROFEME® tube until cream reaches the open nozzle of the tube. At the same time slowly withdraw the plunger of the applicator. The cream will flow into the barrel of the applicator. Fill to the required dose. For example: a 1 mL dose of PROFEME® 10% (100 mg progesterone) needs the flat part of the plunger level with the 1 mL mark. If there are any air bubbles in the measured dose fill slightly past the required dose mark then depress the plunger so that the excess cream flows back into the tube. Stop at the required dose mark. Remove the applicator from the nozzle of the tube and replace the cap firmly on the tube. Depress the plunger of the applicator containing the dose of PROFEME® directly onto the skin (inner arm or upper thigh). Massage the cream into the area until absorbed. Rinse the applicator in warm water after use and replace in box with PROFEME® progesterone cream ready for the next day's application. Each 1 mL of PROFEME® 10% contains 100 mg of progesterone.



Where to apply PROFEME® cream?

Always apply PROFEME® cream to clean dry areas of skin. The best area to use PROFEME® is the inner forearms or the upper thighs. Never apply the cream to broken or damaged skin. Do not use PROFEME® on the genital area. PROFEME® cream should be applied at approximately the same time each day.



How often to apply PROFEME® Cream

Because each woman has a different progesterone requirement there is not a single "correct" dose of PROFEME®. PROFEME® is available in two different strengths (3.2% and 10%) and your doctor will have prescribed the strength and dose suitable for your individual condition.

Should you be unsure of the exact dose and frequency of dose contact your doctor. A dosage guide follows.

Usual dose of PROFEME®

Perimenopausal women (including moderate heavy bleeding, uterine fibroids and mild endometriosis)
Apply 0.3 mL of PROFEME® 10% cream via measured applicator (30 mg progesterone) daily or in divided doses from day 12-26 of menstrual cycle. If a menstrual period starts prior to day 26 cease using PROFEME® and consider the first day of bleeding as day 1 of the new cycle. This is a common occurrence when initiating treatment in perimenopausal women and should be considered a sign that the treatment is having a positive effect. Symptoms abate in 2nd or 3rd month of use. Where symptoms are more severe or unresponsive increase the dose to 100-200 mg (1-2 mL daily).

Premenstrual syndrome (PMS)
Apply 0.3 mL of PROFEME® 10% cream via measured applicator (30 mg progesterone) daily or in divided doses from day 12-26 of menstrual cycle. Significant alterations to this dosage may be made to achieve a crescendo effect 4-5 days prior to menses. Symptoms abate in 2nd or 3rd month of use.

Premenstrual dysphoric disorder (PMDD)
Apply 0.5-1 mL of PROFEME® 10% cream via measured applicator (50-100 mg progesterone) daily or in divided doses from day 12-26 of each menstrual cycle. Significant alteration to this dosage may be made to achieve a crescendo effect 4-5 days prior to menses. Symptoms abate in 2nd or 3rd month of use.

Severe endometriosis, sever menstrual bleeding/flooding and postpartum depression
Apply 1.0 - 2.0 mL of PROFEME® 10% cream via measured applicator (100-200 mg progesterone) daily or in divided doses depending upon the severity of the condition. In reproductive cyclical women initiate treatment on a day 12-26 basis, but this may need to be increased to three weeks use in every four if symptoms/pain emerge upon withdrawal.

Infertility/repeated first-term miscarriage
Luteal phase and first timester corpus luteal support. Apply 1 mL of PROFEME® 10% cream (100 mg progesterone) daily or in divided doses via measured applicator from day 12-26 of each cycle until pregnancy is confirmed and then 1-2 mL daily on a continual basis until at least week 13 or until full term.

Before conceiving, a women prone to miscarriage should use 0.3 mL of PROFEME® 10% cream (30 mg progesterone) from days 12-26 of the cycle until the pregnancy is confirmed. If spotting occurs at week 6 or 7 of pregnancy, a high dose of 100-200 mg progesterone cream (PROFEME® 10%) twice or three times daily. PROFEME® 10% can be used until the baby is full term (40 weeks of gestation).

NOTE: Amount and duration of application for all conditions must be tailored to individual requirements.

If you miss a dose

If you forget to apply your cream, you should apply it as soon as you remember provided this is within 9 hours of your usual time of application.

Otherwise do not apply the cream until the next application time. Missing a dose will not create a significant disruption to your treatment.

If you use too much (overdose)

Because of the way PROFEME® is used, an unintentional overdose is unlikely.

If you think that you or anyone else may have used too much PROFEME®, immediately telephone your doctor or your local Poisons Information Centre for advice.

During PROFEME® use

Do's

Inform your doctor or pharmacist that you are using PROFEME® before starting any other prescribed medicine. Some medicines interact with other medications.

Tell all doctors, dentists and pharmacists who are treating you that you are using PROFEME®.

Do Not's

Do not give PROFEME® to anyone else, even if they have the same symptoms or condition as you. Observe care when driving or operating machinery at the start of using PROFEME until you know how PROFEME® affects you. There is no evidence that PROFEME® will affect your ability to drive or to operate machinery. It is recommended that patients do not swim or shower until at least one hour after application of PROFEME® cream.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using PROFEME®. All medicines can have side effects in some people. Some side effects may need medical attention. Tell your doctor if you notice any of the following that are troublesome or ongoing:

- Skin irritation, for example rash or slight redness and itching of the skin where the cream has been applied. Any irritation will usually disappear within a few days. If it persists contact your doctor or pharmacist.
- Breast tenderness
- Fatigue
- Headache
- Nausea
- Light headedness

These effects are occasionally reported and usually disappear with adjustment of dose.

Tell your doctor if you observe any other side effects not listed above.

After using PROFEME®

Storage

Keep the tube sealed until time of use.

Replace cap firmly on the tube once opened.

Do not transfer the cream out of the original tube into another container. Keep the tube in a cool dry place where the temperature stays below 25°C.

DO NOT FREEZE.

Keep medicines out of reach of children.

Disposal

If your doctor tells you to stop using PROFEME® return your tube to your pharmacy to be correctly disposed of.

Product description

PROFEME® cream is a white opaque odorless cream in a laminated tube. The crimp at the base of the tube has the batch number and expiry date imprinted on it. The tube is boxed and in the box is a consumer information sheet and a graduated measuring applicator.

Ingredients

Each 50 mL tube of PROFEME® 10% contains 5000 milligrams (5000 mg) of progesterone. Each 1mL dose via measured applicator delivers 100 mg of progesterone. Other ingredients in the cream include cetomacrogol 1000, cetostearyl alcohol, almond oil, macadamia nut oil, dl-α-tocopherol acetate (vitamin E acetate), butylated hydroxytoluene, anhydrous citric acid, triethanolamine, Carbomer 940, B&J Phenonip® and purified water.

PROFEME® 10% progesterone creams are available in a 50 mL sealed laminated tube.

Name and Address of Supplier

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