PROFEME® 10
Cream containing 10% w/w (100mg/ml)
Pregnatone 87H (Prog-4 overnight)+0.58mg

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 and 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. Only your doctor can decide if PROFEME® is right for you. If you have any questions about PROFEME®, talk to your doctor or pharmacist. Keep this leaflet with the cream. Do not throw it away.

What PROFEME® is used for?
PROFEME® contains the active ingredient progesterone. The 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, energy levels and wellbeing in women.

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

Prior to using PROFEME®

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 specified to your condition and may 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
To measure the correct dose of cream, gently squeeze the base of the PROFEME® 10 tube until cream reaches the end of the nozzle of the tube. Insert the tip of the applicator into the open nozzle of PROFEME® cream so that the nozzle and the body of the applicator are in contact. Invert the tube and the applicator so the cream will flow with gravity when squeezed. Carefully squeeze the base of the PROFEME® 10 tube and at the same time slowly draw the red plunger. The cream will flow into the barrel of the applicator. Do not try to squeeze the cream into the syringe.

Fill to the required dose. For example: a 0.3ml dose of PROFEME® 10 (30mg of progesterone) needs the flat part of the plunger level with the 0.3ml mark. If there are any air bubbles in the measured dose fill slightly more to remove the air bubbles. Depress the plunger so the excess cream flows back into the tube. Stop at the required dose mark. Remove the applicator from the nozzle and replace the cap firmly on the tube.

Where to apply PROFEME® cream
Always apply PROFEME® cream to clean, dry areas of skin. The best area to use PROFEME® cream is on the inner arms or the upper thighs. Never apply the cream to broken or damaged skin. PROFEME® cream should be applied at approximately the same time each day.

How often to apply PROFEME® cream
Each woman has a different progesterone requirement there is not a single "correct" dose of PROFEME®. Should you have any questions about the dose or frequency of dose, contact your doctor. A dosage guide follows.

Usual dose of PROFEME® cream
Pregnancy women (including those with heavy bleeding, fibroids and mild endometriosis), 5ml of PROFEME® cream via measured applicator (30mg progesterone) daily or in divided doses from day 12-26 of each 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 the treatment is having a positive effect. Symptoms usually settle in the 2nd or 3rd month of use. Where symptoms are more severe or unresponsive your doctor may need to increase the dose to 100-200mg (1-2ml) daily.

Premenstrual syndrome (PMS), Apply 0.3ml of PROFEME® 10% cream via measured applicator (30mg progesterone) daily or in divided doses from day 12-26 of each menstrual cycle. Significant alterations to this dosage may be made to achieve a crescent effect 4.5 days prior to menar. Symptoms generally settle in the 2nd or 3rd month of use.

Premenstrual dysphoric disorder (PMDD) Apply 0.5-1ml of PROFEME® cream via measured applicator (50-100mg progesterone) daily or in divided doses from day 12-26 of each menstrual cycle. Significant alterations to this dosage may be made to achieve a crescent effect 4.5 days prior to menar. Symptoms generally settle in the 2nd or 3rd month of use. Severe endometrioadhes, severe menstrual bleeding/bleeding and postpartum depression. Apply 1.0 - 2.0ml of PROFEME® 10% cream via measured applicator (100-200mg progesterone) daily or in divided doses from day 12-26 of each menstrual cycle. This may need to be increased to 3 weeks in every four if symptoms remain unresolved. Impetigo/Repetted Freckle-Tacmiserum Lutinal phase and first trimester corpus luteal support, Apply 1ml of PROFEME® 10% cream (100mg progesterone) daily or in divided doses from day 12-26 of each menstrual cycle until pregnancy is confirmed. If spotting occurs at week 6 or 7 of pregnancy, use a high dose (100-200mg progesterone cream) (PROFEME®) 10% twice or three times daily. PROFEME® 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, providing it is less than 6 hours of the usual time of application. Otherwise do not apply the cream until the next application is due. 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 pharmacist for advice.

During PROFEME® use
Do's
Inform your doctor or pharmacist that you are using PROFEME® when driving or operating any machinery at the start of PROFEME® until you know how PROFEME® affects you. PROFEME® will affect your ability to drive or operate machinery. It is recommended that patients do not swim or shower until at least four hours after application of PROFEME® cream.

Do not's
Do not give PROFEME® to anyone else, even if they have the same symptoms or condition as you. This is because other medications may affect how PROFEME® affects you. PROFEME® will affect your ability to drive or operate machinery. It is recommended that patients do not swim or shower until at least four hours 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. Some side effects are serious and 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 is applied. This may usually disappear within a few days. If it persists contact your doctor or pharmacist.
• Breast tenderness
• 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®
Keep the cream tube sealed until use time. 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 pharmacist to be disposed of correctly.

Product description
PROFEME® cream is a white, odourless cream in a laminated tube. The crim 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 50ml tube of PROFEME® 10% contains 5000 milligrams (5000mg) of progesterone. Each Fine dose via measured applicator delivers 100mg of progesterone. Other inactive ingredient includes cocamidopropyl betaine, ceteareth-100, cetearyl alcohol, parfum, linalool, lauryl alcohol, sorbitan monooleate, butyldiglycol, caprylic/capric triglyceride, phenoxyethanol, ethylhexylglycerine, cynanocarboxylic acid, tocopherol, triclosan, triclocarban, Carbomer 940, B&J Phenoxy alcohol and purified water. PROFEME® 10% is supplied in a 50ml seamed laminated tube.

Name and Address of Supplier
Llewellyn Pharmaceuticals Pty Ltd Unit 2/315 Harrison Street, West Leederville, 6007 Western Australia, AUSTRALIA
Postal Address P O Box 241, West Leederville, 6901 Western Australia, AUSTRALIA
Telephone: +61 8 9388 0096 Toll-Free phone (Australia): 1800 627 506 Fax: +61 8 9388 0096
USA & Canada Telephone: 1-800-951-7813 Toll Free: 1-888-961-7650 Website: www.llewellynpharm.com.au Email: info@llewellynpharm.com.au
Date of Preparation: December 2016. PROFEME® is a registered trademark.