

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some of the common questions about PRO-FEME®. 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 PRO-FEME® against the benefits it can have for you.

**If you have any concerns about using PRO-FEME® talk to your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

### What PRO-FEME® is used for

PRO-FEME® 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 PRO-FEME® provides progesterone to address this deficiency.

The skin is very good at absorbing progesterone and PRO-FEME® is a clean, simple and effective means of getting progesterone into the body.

### Prior to using PRO-FEME®

PRO-FEME® cream should not be used if you are allergic to progesterone, or any of the ingredients contained within PRO-FEME®. These are listed at the end of this leaflet.

This product contains *almond oil* and *macadamia nut oil*.

Do not use PRO-FEME® 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 PRO-FEME®.

If you are taking other medications check with your doctor or pharmacist before using PRO-FEME®.

PRO-FEME® 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 PRO-FEME® from being absorbed.

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

Do not use PRO-FEME® if the tamper proof seal at the top of the tube is damaged or broken.

PRO-FEME® is not indicated for use in children.

### How to use PRO-FEME®

Your doctor or pharmacist will explain how to apply PRO-FEME®.

Follow all directions exactly as they are explained. If you are unclear clarify with your doctor or pharmacist prior to use.

The dose of PRO-FEME® will be determined for you by your doctor. This dose is 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 turn it upside down. Fit the triangle onto the top of the tube.

Twist to open. Dispose of the broken seal and replace the cap firmly after using the cream.

#### Measuring the correct dose of PRO-FEME® Cream

A small plastic applicator with 1 unit graduations is provided inside the PRO-FEME® box.

Your doctor will have determined what dose is appropriate for you.

Squeeze the tube so that the prescribed dose of cream covers the applicators graduated guidelines.

#### Where to apply PRO-FEME® cream

Always apply PRO-FEME® cream to clean dry areas of skin.

The best area to use PRO-FEME® is the inner forearms or the upper thighs.

Never apply the cream to broken or damaged skin.

Do not use PRO-FEME® on the genital area.

PRO-FEME® cream should be applied at approximately the same time each day.

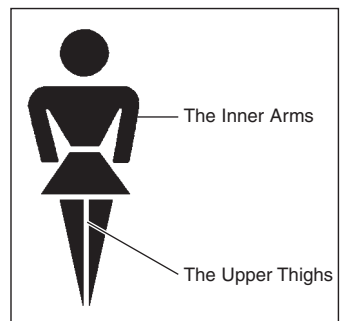
#### How often to apply PRO-FEME® cream

Because each woman has a different progesterone requirement there is not a single "correct" dose of PRO-FEME®.

PRO-FEME® 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 or pharmacist.

A dosage guide follows.



# Usual dose of PRO-FEME®

## Menopausal Women

Apply 2 units of PRO-FEME® 3.2% cream (32mg progesterone) daily or in divided doses for 25 days per calendar month.

## Peri-menopausal

Apply 2 units of PRO-FEME® 3.2% cream (32mg progesterone) daily or in divided doses from day 12-26 days of menstrual cycle.

## Pre-menstrual Syndrome

Apply 2 units of PRO-FEME® 3.2% cream (32mg progesterone) daily or in divided doses from day 12-26 days of menstrual cycle. Significant alterations to this dose may be made to achieve a crescendo effect 4-5 days prior to menses.

## Endometriosis or Post Natal Depression

Apply 3 units of PRO-FEME® 10% w/w cream (150mg progesterone) daily or in individual doses for 21 days per calendar month.

**NOTE:** Amount and duration of application 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 PRO-FEME® is used, an unintentional overdose is unlikely.

If you think that you or anyone else may have used too much PRO-FEME®, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice.

# During PRO-FEME® use

## Do's

Inform your doctor or pharmacist that you are using PRO-FEME® 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 PRO-FEME®.

## Dont's

Do not give PRO-FEME® 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 PRO-FEME® until you know how PRO-FEME® affects you. There is no evidence that PRO-FEME® 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 PRO-FEME® cream.

# Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using PRO-FEME®.

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 PRO-FEME®

## 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 leave it in the car on a hot day or on window sills.

DO NOT FREEZE

Keep medicines out of reach of children.

## Disposal

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

# Product description

## What it looks like

PRO-FEME® cream is a white opaque odourless cream in a white 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 plastic graduated applicator.

## Ingredients

PRO-FEME® is available in two strengths, 3.2% and 10% w/w.

Each 50 gram tube of 3.2% PRO-FEME® contains 1600 milligram (1600mg) of progesterone. Each 2 unit (1 gram) dose delivers approximately 32mg of progesterone.

Each 50 gram tube of 10% PRO-FEME® contains 5000 milligram (5000mg) of progesterone. Each 2 unit (1 gram) dose delivers approximately 100mg of progesterone.

Other ingredients in the cream include cetomacrogol 1000, cetostearyl alcohol, almond oil, macadamia nut oil, dl- $\alpha$ -tocopherol acetate (Vitamin E acetate), butylated hydroxytoluene, anhydrous citric acid, triethanolamine, Carbomer 940, B&J Phenonip, hydroxybenzoates, phenoxyethanol and purified water.

PRO-FEME® is available in a 50 gram sealed laminated tube.

## Sponsor

### **Lawley Pharmaceuticals**

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PRO-FEME® is a registered trademark.

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