

PATIENT INFORMATION LEAFLET

PROGESTERONE CREAM

Read all of this leaflet carefully because it contains important information for you.

This product is available without a doctor's prescription, however you still need to use Progesterone Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider if you need more information or advice.
- You need to see your healthcare provider if your symptoms worsen or do not improve after 30 days.

Scheduling status:
To be determined.

Proprietary name and dosage form:
Progesterone cream 50mg.

Composition:
Each scoop (1ml) of Progesterone cream contains 30mg bio-identical progesterone (BP/USP) 3% w/v (30mg/ml), in a liposomal, non-steroidal, xenoestrogen-free squalene base for improved systemic absorption.

Pharmacological Classification:
A.32.36 Others.

Pharmacological action:

Progesterone is primarily made by the ovaries but is also made in smaller amounts by the adrenal glands in both women and men and by the testes in men. Progesterone is a precursor to many other steroid hormones such as cortisol, testosterone and estrogen (estradiol, estrone, and estrin).

Women: The levels of progesterone in a woman's body rise and fall drastically within each monthly cycle. During ovulation (day 14) the production of progesterone rises rapidly. After 10 to 12 days if the egg is not fertilized, the production of progesterone falls rapidly, which triggers a period/menstruation. One of progesterone's most important functions is to balance the effects of estrogen. At menopause a woman's estrogen levels drop by between 40 - 60%. This drop signals the end of the menstrual cycle. Progesterone levels, however, may drop to close to 0% in some women. At menopause the adrenals and other organs take over the production of hormones, in particular testosterone and estrogen, and to a lesser extent progesterone. In cases of adrenal exhaustion and other health issues the body cannot always

compensate, which will cause further hormone imbalances. Progesterone can play an important role in the enhancement of overall hormonal balance.

Men: Adequate levels of progesterone in men are important to health as it is the precursor to adrenal cortical hormones and testosterone. The metabolic actions of the prostate gland are largely determined by especially estradiol, progesterone and testosterone, which are made by the testes. Therefore putting progesterone back into the body will assist in maintaining a healthy prostate.

Indications:

Progesterone is used topically or intra-vaginally as an alternative to oral hormone replacement therapy or as a component of hormone replacement therapy.

Contra-indications:

Hypersensitivity to any of the ingredients.

Warnings:

Not to be used by pregnant or breast-feeding women or by individuals under the age of 18 unless under the supervision of a medical practitioner. Do not exceed recommended dosages unless on the advice of a healthcare provider. If you are on prescription medicine or suffering from any medical condition, it is advisable to seek medical advice before beginning any new supplement or remedy.

Interactions:

There are no known interactions with natural progesterone cream at recommended dosages.

Pregnancy and breast-feeding:

Not to be used by pregnant or breast-feeding women unless under the supervision of a medical practitioner.

Dosage and directions for use:

Progesterone cream can be used topically or intra-vaginally. **WOMEN:** If you are not obtaining the desired results please consult with your medical practitioner as you may require an upwards adjustment in the dosage you are using. Apply to the skin once daily or as directed by your medical practitioner.

Pre-menopausal from age 28:

Use 1ml level scoop once daily - use from day 10-25 of monthly cycle or as prescribed by your medical practitioner.

Post-menopausal:

Use 1ml level scoop once daily, taking a break for 3 consecutive days per month, or as prescribed by your medical practitioner. Some medical practitioners propose a cycling dose regimen.

For cycling purposes use the regime as outlined:



Use $\frac{1}{4}$ (0.25ml) to $\frac{1}{2}$ (0.5ml) scoop once daily from day 1-10, then use one 1ml scoop once daily from day 11-25, then take a break for 3 consecutive days. Start again by using a $\frac{1}{4}$ (0.25ml) to $\frac{1}{2}$ (0.5ml) scoop once daily from day 1-10, continue with the protocol as indicated. Or use as directed by your medical practitioner.



MEN: Use $\frac{1}{2}$ (0.5ml) scoop each night before going to bed. Men do NOT need days off.

Directions for application of the cream:

- Progesterone cream to be applied at the same time every day, preferably every morning or evening (or as directed by your healthcare provider), to clean, dry, intact skin.
- Area of application must be washed with hot water and patted dry. Ensure that area is completely dry before you apply the cream.
- Do not apply any other creams to this area before applying the Progesterone cream.
- Apply and rub the cream to one or more of the application sites as per the illustration. Rub the cream into your skin, until it disappears.
- Rotate sites to avoid saturation.
- After application wash hands with soap and water.
- Allow the application sites to dry before getting dressed.
- Do not bath for forty minutes after application.
- Do not exercise for two hours after application.

Directions for use with an applicator:

The cream can also be used internally/vaginally by using an applicator (not supplied).

- Use a 1ml syringe to fill the applicator.
- Carefully insert the end of the applicator as deeply as possible into the vagina and then push in plunger to deposit the cream.
- Remove the applicator from the vagina and discard it as well as syringe.

Side-effects and special precautions:

Side effects are rare and may include breast tenderness and swelling, fluid retention or slight vaginal bleeding. Dizziness, nausea, fatigue, headaches and light-headedness have been

reported occasionally and usually disappear with adjustment of the dose. Bise contains lecithin which can cause a local skin redness or itching in 1-2% of users.

Known symptoms of overdose and particulars of its treatment:

See Side-effects and special precautions. Treatment is symptomatic and supportive.

Storage instructions:

Store in a cool (below 25°C), dry place. Protect from moisture. Keep container tightly closed. Keep out of reach of children.

Presentation:

Outer carton containing a plastic tub (50ml) with screw-on lid. Supplied with a 1ml plastic scoop.

Identification:

Soft, yellow cream.

Registry Number:

001580

Name and Business Address of Applicant:

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