PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Progesterone
Form: Topical Cream

Drug Class: Progestin (Natural Steroid Hormone)

Mechanism of Action[1,2]**:**
Progesterone is a steroid hormone that is produced from ovaries. Progesterone supplementation is intended to bind to progesterone receptors in target tissues, inducing secretory changes in the endometrium, promoting mammary gland development, relaxing uterine smooth muscle, and maintaining pregnancy. It may also exhibit antigonadotrophic effects by suppressing pituitary gonadotropin secretion, thereby inhibiting follicular maturation and ovulation.

Indications Commonly Prescribed for:

- Prevention of endometrial hyperplasia in nonhysterectomized, postmenopausal women receiving conjugated estrogens.
- Treatment of secondary amenorrhea.
- Assisted reproductive technology (ART) for infertile women with progesterone deficiency.
- Luteal phase support in in vitro fertilization (IVF) cycles.
- Prevention of recurrent spontaneous preterm birth in women with a singleton pregnancy and prior spontaneous preterm singleton birth.

Before Use: Let your healthcare provider know if you have any medication allergies before you take this compounded preparation. Let your healthcare provider know if you have any liver or kidney problems. Let your healthcare provider know of all supplements you are currently taking.

Contraindications:

- Known hypersensitivity to progesterone or any component of the formulation.
- Undiagnosed abnormal genital bleeding.
- History of breast cancer or other hormone-sensitive malignancies.
- Active or history of thromboembolic disorders (e.g., deep vein thrombosis, pulmonary embolism).
- Liver dysfunction or disease.
- Known or suspected pregnancy (when used for non-pregnancy-related indications).

Cautions: Let your Healthcare provider know if you experience any adverse side effects.

How to Use: This compounded preparation is in the form of a topical cream. The cream is a special container that will administer 0.25ml dose. Clean desired area prior to use. To administer remove the protective covering on the top of the dispenser. Place the jar on a flat surface. Using clean, dry hands, gently press down on the top of the pump. This will dispense a measured amount of cream through the center opening. Confirm the cream has exited the holes at the top of the dispenser. Apply the cream onto the desired area. Continue to rub the area until the cream is evenly dispersed over the desired area. Replace the protective cover and store the device until next dose. If you miss a dose apply as soon as you remember, but not at the time for the next dose. The desired results may take up to several weeks.

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Warnings and Precautions:

- Cardiovascular Disorders: Progesterone therapy should not be used for the prevention of cardiovascular disease or dementia.
- Breast Cancer: Increased risk observed with combined estrogen and progestin therapy.
- Probable Dementia: Elevated risk in postmenopausal women aged 65 and older receiving combined therapy.
- Mood Disorders: Use with caution in patients with a history of depression; monitor for exacerbation of symptoms.
- Fluid Retention: Exercise caution in patients with conditions that may be exacerbated by fluid retention, such as epilepsy, migraine, asthma, cardiac or renal dysfunction.
- Sedation/dizziness: Take at bedtime; caution driving/operating machinery

Adverse Reactions:

Common:

- Breast tenderness
- Bloating
- Mood swings
- Drowsiness, Dizziness, Headache
- Fluid retention

Serious:

- Thromboembolic events
- Visual disturbances
- Severe allergic reactions

Interactions:

- CYP3A4 Inducers (e.g., rifampin, carbamazepine): May decrease progesterone plasma concentrations, reducing efficacy.
- CYP3A4 Inhibitors (e.g., ketoconazole): May increase progesterone plasma concentrations, enhancing effects and potential side effects.
- Herbal Products (e.g., St. John's Wort): May reduce progesterone effectiveness by inducing hepatic enzymes.

Use in Specific Populations:

- Pregnancy: Use only if clearly needed and prescribed by a healthcare provider.
- Lactation: Progesterone is excreted in breast milk; caution is advised.
- Pediatrics: Safety and efficacy have not been established in pediatric patients.
- Geriatrics: Use with caution; increased sensitivity in some older individuals cannot be ruled out.

Storage:

- Store in original container at room temperature (up to 30°C or 86°F)
- Store in a cool dry place away from heat, sunlight, and moisture

Monitoring Parameters:

- Regular physical examinations, including breast and pelvic exams.
- Monitoring for signs of thromboembolic disorders.
- Assessment of mood changes or depressive symptoms.
- Periodic liver function tests in long-term use.

Citations:

1. Cable JK, Grider MH. Physiology, Progesterone. [Updated 2022 May 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK558960/
2. Goletiani NV, Keith DR, Gorsky SJ. Progesterone: review of safety for clinical studies. Exp Clin Psychopharmacol. 2007 Oct;15(5):427-44. doi: 10.1037/1064-1297.15.5.427. PMID: 17924777.