PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Progesterone
Form: Sublingual Rapid Dissolve Tablet

Drug Class: Progestogens (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 postmenopausal women receiving estrogen therapy.
- 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 health care provider know if you have any medication allergies before you take this compounded preparation. Let your health care 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 sublingual rapid dissolve tablet. Place tablet under tongue to dissolve completely. Do not chew or crush the capsule. Once the tablet has fully dissolved, do not rinse your mouth, brush your teeth, or consume food or beverages for at least five minutes to allow absorption. If you miss a dose, take as soon as you remember, but not at the time for the next dose. The desired results may take up to several weeks.

Compounded medications are not FDA-approved and may differ in risks, benefits, and side effects from FDA-approved products. These statements have not been evaluated by the FDA and are not intended to diagnose, treat or cure any disease or condition and do not indicate any claims of safety or efficacy. Individual results may vary.

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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.

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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.

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