# Information For the Use Progesterone (Natural Micronized) (300mg)

# Peblegest 300 Softgel Capsule

Progesterone (Na	tural Micronized) 300mg	
Softgel		

# **Description**

Progesterone (Natural Micronized) 300mg Softgel is a high-potency, bioavailable form of progesterone, designed to provide effective supplementation for patients with progesterone deficiency or those undergoing hormone replacement therapy (HRT). Derived from plant sources (usually yam), this micronized progesterone is identical to the naturally occurring progesterone in the human body, ensuring optimal compatibility and action. The micronization process enhances absorption, allowing for better bioavailability and efficacy, particularly in patients who need a higher dose of progesterone for therapeutic purposes.

# **Composition**

Each softgel capsule contains:

- Progesterone (Natural Micronized) 300mg
- Excipients: Capsule ingredients may include soybean oil or safflower oil as a base, with gelatin used to form the softgel shell, and other stabilizers as necessary.

### **Pharmacological Action**

Progesterone (Natural Micronized) 300mg Softgel acts on several biological pathways to promote hormonal balance and improve various conditions related to progesterone deficiency.

• Supports the Luteal Phase: Progesterone is critical for the luteal phase of the menstrual cycle, where it prepares the

- uterine lining for the potential implantation of a fertilized egg.
- Maintains Pregnancy: It helps maintain a healthy uterine environment, preventing premature contractions and supporting early pregnancy.
- Regulates Menstrual Cycle: Progesterone is a key hormone for regulating the menstrual cycle, particularly in cases of irregular or absent menstruation caused by hormonal imbalance.
- Prevents Endometrial Hyperplasia: In hormone replacement therapy (HRT), progesterone prevents the overgrowth of the uterine lining (endometrial hyperplasia), a potential side effect of estrogen therapy.

#### **Indications**

Progesterone (Natural Micronized) 300mg Softgel is commonly prescribed for the following conditions:

- 1. Hormone Replacement Therapy (HRT): For postmenopausal women who require progesterone to complement estrogen therapy, reducing the risk of endometrial hyperplasia and managing menopausal symptoms.
- 2. Progesterone Deficiency: Used to treat conditions associated with low progesterone levels, such as luteal phase defect, Polycystic Ovary Syndrome (PCOS), or other menstrual irregularities.
- 3. Pregnancy Support: For women undergoing fertility treatments (e.g., in vitro fertilization [IVF] or intrauterine insemination [IUI]) or those with a history of recurrent miscarriage due to low progesterone.
- 4. Abnormal Uterine Bleeding: To address abnormal uterine bleeding caused by hormonal imbalances or irregular cycles.

5. Menstrual Disorders: To help manage irregular, painful, or absent menstruation due to hormonal disruptions.

# **Dosage and Administration**

# **Recommended Dosage:**

- For Hormone Replacement Therapy (HRT): The typical dose is 1 softgel (300mg) daily, taken at bedtime. Dosage adjustments can be made based on individual needs and treatment response.
- For Progesterone Deficiency: The usual starting dose is 1 softgel (300mg) per day, though your healthcare provider may recommend adjustments based on the specific condition and how you respond to the medication.
- For Pregnancy Support: In fertility treatments or for women with a history of miscarriage due to low progesterone, the recommended dose is often 1 softgel (300mg) daily or as directed by the treating physician.

#### **Administration:**

- Route of Administration: Oral (by mouth).
- Instructions: Swallow the softgel capsule whole with a full glass of water. It is generally recommended to take the softgel at night to minimize possible gastrointestinal discomfort or drowsiness.

#### **Contraindications**

Progesterone (Natural Micronized) 300mg Softgel is contraindicated in the following situations:

- Hypersensitivity to progesterone or any other components of the formulation.
- Active or history of breast cancer or other hormone-sensitive cancers.

- Severe liver disease, including cirrhosis or active liver dysfunction.
- Unexplained vaginal bleeding without a definitive diagnosis.
- History of thromboembolic events, such as deep vein thrombosis (DVT), stroke, or heart attack.
- Ectopic pregnancy or molar pregnancy.
- Known or suspected pregnancy conditions like preeclampsia or HELLP syndrome.

# Warnings and Precautions

- Blood Clot Risk: Women with a history of blood clots or other vascular conditions should use progesterone cautiously, as it may increase the risk of blood clotting.
- Liver Function: Caution is required for those with liver disease, as progesterone may affect liver function.
- Mood and Psychological Effects: Some individuals may experience mood swings, irritability, or depression. Discontinue use and consult a doctor if any psychological symptoms occur.
- Hypertension: If you have a history of high blood pressure, regular monitoring is recommended as progesterone may exacerbate hypertension.
- Fluid Retention: Progesterone can cause fluid retention, particularly in individuals with pre-existing kidney, heart, or liver conditions.
- Pregnancy and Breastfeeding: Use during pregnancy should be supervised by a healthcare provider. While progesterone is often used to support pregnancy, it should be prescribed cautiously during breastfeeding.

#### **Side Effects**

#### **Common Side Effects:**

- Drowsiness or fatigue
- Headache

- Abdominal discomfort or bloating
- Breast tenderness or enlargement
- Weight gain due to fluid retention
- Changes in mood (irritability, anxiety)
- Breakthrough bleeding or spotting

### **Serious Side Effects:**

- Severe allergic reactions (difficulty breathing, swelling of the face or throat)
- Signs of blood clots (pain, swelling, redness in the legs, sudden shortness of breath)
- Severe liver symptoms (yellowing of the skin or eyes, severe abdominal pain)
- Unusual vaginal bleeding
- Severe headaches or changes in vision

## **Drug Interactions**

Progesterone (Natural Micronized) 300mg Softgel may interact with the following:

- Anticoagulants (blood thinners): Increased risk of bleeding when combined with anticoagulants.
- Corticosteroids: Enhanced effects when used with corticosteroids.
- Anticonvulsants: Some anti-seizure drugs may reduce the effectiveness of progesterone.
- Estrogen: When used together in hormone replacement therapy, progesterone helps protect the uterine lining from estrogen's effects.

# **Storage Instructions**

- Temperature: Store at room temperature (15°C to 30°C).
- Protection: Keep the softgel in its original packaging to protect it from moisture and light.
- Shelf Life: Do not use after the expiration date printed on the packaging.

#### **Presentation**

- Form: Softgel capsule
- Strength: 300mg of natural micronized progesterone per capsule
- Pack Size: Available in bottles of 10, 20, or more capsules.

#### Conclusion

Progesterone (Natural Micronized) 300mg Softgel provides a highly effective and bioavailable form of progesterone for supporting hormonal balance, managing progesterone deficiency, and promoting reproductive health. The micronized form ensures enhanced absorption, providing reliable therapeutic benefits for women undergoing hormone replacement therapy or those seeking pregnancy support. As with any hormonal therapy, it should be taken under the guidance of a healthcare provider to ensure safety and efficacy.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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