

Peblegest 400 Softgel Capsule

**Progesterone (Natural Micronized) 400mg
Softgel**

Description

Progesterone (Natural Micronized) 400mg Softgel is a highly bioavailable, plant-derived form of progesterone that is identical to the naturally occurring hormone in the human body. This formulation uses micronization to enhance absorption, ensuring maximum efficacy and compatibility with the body's progesterone receptors. Progesterone plays a critical role in reproductive health, particularly in regulating the menstrual cycle, maintaining pregnancy, and supporting hormone replacement therapy (HRT) in postmenopausal women. The 400mg dose is typically prescribed for those requiring higher levels of progesterone for therapeutic purposes.

Composition

Each softgel capsule contains:

- **Progesterone (Natural Micronized) – 400mg**
 - **Excipients:** Base oils (such as soybean or safflower oil), gelatin (for capsule formation), and other stabilizers as necessary.
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Pharmacological Action

Progesterone is a steroid hormone essential for regulating the menstrual cycle and pregnancy. Progesterone (Natural Micronized) 400mg Softgel works through several key mechanisms:

- **Supports Pregnancy:** Progesterone helps maintain the uterine lining, preventing early pregnancy loss. It supports

implantation and sustains a healthy environment for fetal development during pregnancy.

- **Regulates Menstrual Cycle:** By balancing estrogen, progesterone helps regulate menstruation, particularly in cases of irregular cycles or hormonal imbalances.
 - **Hormone Replacement Therapy (HRT):** In postmenopausal women, progesterone helps balance estrogen's effects, protecting against the risk of endometrial hyperplasia (overgrowth of the uterine lining) caused by estrogen therapy.
 - **Neuroprotective Effects:** Progesterone has been shown to exert some protective effects on the nervous system, promoting cognitive function and mood stabilization.
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Indications

Progesterone (Natural Micronized) 400mg Softgel is commonly prescribed for the following conditions:

1. **Hormone Replacement Therapy (HRT):** For postmenopausal women requiring progesterone to complement estrogen therapy.
2. **Progesterone Deficiency:** Treatment for conditions related to low progesterone, such as luteal phase defects, Polycystic Ovary Syndrome (PCOS), and irregular cycles.
3. **Pregnancy Support:** To support early pregnancy in women with low progesterone or those undergoing fertility treatments (e.g., IVF or IUI).
4. **Menstrual Disorders:** Used to manage abnormal bleeding, irregular menstruation, or as part of a treatment for anovulatory cycles.
5. **Recurrent Miscarriage:** In cases where low progesterone has been linked to recurrent early pregnancy loss.

Dosage and Administration

Recommended Dosage:

- **For Hormone Replacement Therapy (HRT):** Typically, 1 softgel (400mg) is taken daily, often at night, to minimize side effects such as drowsiness or gastrointestinal discomfort.
- **For Progesterone Deficiency:** A common starting dose is 1 softgel (400mg) daily. The dosage may vary depending on the severity of progesterone deficiency and how the patient responds to the therapy.
- **For Pregnancy Support:** In assisted reproductive treatments (e.g., IVF), the recommended dosage is often 1 softgel (400mg) per day, or as prescribed by the fertility specialist.
- **For Menstrual Disorders:** The usual dose is 1 softgel (400mg) per day, taken as directed by the healthcare provider.

Administration:

- **Route of Administration:** Oral (by mouth).
- **Instructions:** Swallow the softgel whole with a full glass of water. It is generally advised to take the softgel before bedtime to reduce the likelihood of drowsiness during the day.

Contraindications

Progesterone (Natural Micronized) 400mg Softgel is contraindicated in the following situations:

- Hypersensitivity to progesterone or any component of the formulation.
- Active or history of breast cancer or other hormone-sensitive cancers.
- Severe liver disease (e.g., cirrhosis).
- Unexplained vaginal bleeding.

- History of blood clots (e.g., deep vein thrombosis, pulmonary embolism, stroke).
- Ectopic pregnancy.
- Molar pregnancy.
- Pregnancy (in cases of unexplained abnormal uterine bleeding).

Warnings and Precautions

- **Thromboembolic Risk:** There is an increased risk of blood clots in women with a history of thrombosis or those with known risk factors. Women on progesterone should be closely monitored for signs of blood clotting.
- **Liver Function:** Regular liver function tests are advised for patients with pre-existing liver conditions.
- **Mood Changes:** Some women may experience mood swings, anxiety, or depression. Consult a healthcare provider if these symptoms worsen.
- **Fluid Retention:** Progesterone may cause fluid retention, and it should be used cautiously in women with a history of heart, kidney, or liver disease.
- **Pregnancy and Breastfeeding:** Use during pregnancy should be prescribed only if the benefits outweigh the risks. Although progesterone is safe for pregnancy support, its use should be monitored. Its safety during breastfeeding is not fully established.

Side Effects

Common Side Effects:

- Drowsiness, fatigue, or dizziness
- Breast tenderness or enlargement
- Headaches
- Abdominal bloating or discomfort
- Weight gain due to fluid retention
- Irregular vaginal bleeding or spotting
- Mood swings, irritability, or depression

Serious Side Effects:

- Allergic reactions (difficulty breathing, swelling of the face or throat)
 - Deep vein thrombosis, pulmonary embolism, or stroke
 - Severe liver dysfunction (yellowing of the skin or eyes)
 - Signs of a miscarriage or abnormal bleeding
 - Unusual headache, vision changes, or high blood pressure
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Drug Interactions

Progesterone (Natural Micronized) 400mg Softgel may interact with:

- **Anticoagulants (blood thinners):** Progesterone may reduce the effects of blood thinners, increasing the risk of clotting.
 - **Anticonvulsants:** Certain anti-seizure medications may reduce the effectiveness of progesterone.
 - **Estrogen:** When used together, estrogen and progesterone balance the effects on the uterine lining, but this combination should be monitored closely.
 - **Corticosteroids:** The combination with corticosteroids may increase the risk of fluid retention.
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Storage Instructions

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

- **Form:** Softgel capsule
 - **Strength:** 400mg of natural micronized progesterone per capsule
 - **Pack Size:** Available in bottles of 10, 20, or more softgel capsules.
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Conclusion

Progesterone (Natural Micronized) 400mg Softgel offers a highly effective form of progesterone therapy for women experiencing progesterone deficiency or those undergoing fertility treatments. With its improved absorption through micronization, it provides reliable support for menstrual regulation, pregnancy maintenance, and hormone replacement therapy. It should be used under the guidance of a healthcare provider to ensure safety and optimal therapeutic results.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113

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