

# Peblegest 100 Softgel Capsule

## Progesterone (Natural Micronized) 100mg Softgel

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### Description

Progesterone (Natural Micronized) 100mg Softgel is a natural form of progesterone that is micronized to enhance absorption in the body. It is primarily used in hormone replacement therapy (HRT), to support pregnancy in certain cases, and for treating menstrual disorders caused by progesterone deficiency. Unlike synthetic forms of progesterone, natural micronized progesterone is derived from plant sources (usually yam) and is chemically identical to the progesterone produced by the body.

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### Composition

Each softgel of Progesterone (Natural Micronized) 100mg contains:

- Progesterone (Natural Micronized) – 100mg
  - Excipients: The softgel contains additional excipients, such as oils (e.g., soybean oil, safflower oil), gelatin (for the capsule shell), and other stabilizers as per the formulation.
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### Pharmacological Action

Micronized progesterone is absorbed more efficiently than regular progesterone due to its smaller particle size. Once in the bloodstream, it performs the following physiological roles:

- Supports the Luteal Phase: Progesterone is essential for the second half of the menstrual cycle (luteal phase). It prepares the uterus lining for the implantation of a fertilized egg.
- Regulates the Menstrual Cycle: Progesterone helps maintain a regular menstrual cycle, especially in women with progesterone deficiencies or imbalances.
- Supports Pregnancy: In pregnancy, progesterone plays a critical role in

maintaining the uterine lining, preventing premature contractions, and supporting fetal development.

- Prevents Estrogen-Induced Endometrial Hyperplasia: In hormone replacement therapy, progesterone prevents the overgrowth of the endometrial lining caused by estrogen.
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### Indications

Progesterone (Natural Micronized) 100mg Softgel is indicated for the following conditions:

1. Hormone Replacement Therapy (HRT): For postmenopausal women who are undergoing estrogen replacement therapy to reduce the risk of endometrial hyperplasia.
  2. Progesterone Deficiency: Used to treat conditions related to low progesterone levels, including:
    - Irregular menstrual cycles
    - Luteal phase defects
    - Premenstrual syndrome (PMS)
  3. Support for Pregnancy: It is commonly prescribed for women with progesterone deficiency or those undergoing fertility treatments such as in vitro fertilization (IVF) or intrauterine insemination (IUI).
  4. Prevention of Miscarriage: In some cases, progesterone is used to reduce the risk of miscarriage in women with a history of recurrent pregnancy loss.
  5. Abnormal Uterine Bleeding: Used for treating abnormal uterine bleeding due to hormonal imbalance.
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### Dosage and Administration

#### Recommended Dosage:

- For Hormone Replacement Therapy (HRT): The usual dose is 1 softgel (100mg) daily, typically taken at bedtime, to help minimize potential sedation. The dosage may be

adjusted depending on individual needs, and a healthcare provider will determine the appropriate dosage.

- **For Progesterone Deficiency:**  
Typically, 1 softgel (100mg) is taken once daily. Dosage may vary based on the medical condition and the doctor's recommendations. In cases of luteal phase support during fertility treatments, a higher dose may be prescribed.
- **For Pregnancy Support:**  
1 softgel (100mg) is often administered once or twice daily during early pregnancy, especially if progesterone levels are insufficient to maintain the pregnancy. The dose and frequency may be adjusted by the healthcare provider based on individual needs.

#### Administration:

- **Route of Administration:** Oral (by mouth).
- **Instructions:** Swallow the softgel capsule whole with a glass of water. It is usually recommended to take the capsule at night or with food to minimize any potential gastrointestinal discomfort. Follow the dosage schedule as prescribed by your healthcare provider.

#### Contraindications

Progesterone (Natural Micronized) 100mg Softgel is contraindicated in the following conditions:

- Hypersensitivity to progesterone or any of the excipients in the formulation.
- Active or history of breast cancer, ovarian cancer, or other hormone-dependent tumors.
- Severe liver disease (such as cirrhosis or active liver dysfunction).
- Unexplained vaginal bleeding without a clear diagnosis.
- History of thromboembolic disorders (e.g., deep vein thrombosis, pulmonary embolism, or stroke).
- Pregnancy-related conditions such as ectopic pregnancy or molar pregnancy.
- History of or current arterial disease, such as stroke or heart disease.

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#### Warnings and Precautions

- **Thromboembolic Disorders:** There is an increased risk of blood clots, particularly in women who have a history of deep vein thrombosis, stroke, or heart attack. Progesterone should be used with caution in such cases.
- **Liver Disease:** Patients with liver disease should be monitored regularly, as progesterone may affect liver function.
- **Depression and Mood Changes:** Progesterone may cause mood swings, depression, or anxiety in some individuals. If symptoms of depression or other mood changes occur, medical advice should be sought.
- **Breast Cancer:** Women with a history of breast cancer should avoid using progesterone, as it may stimulate the growth of estrogen-sensitive tumors.
- **Blood Sugar Levels:** In diabetic patients, progesterone may influence blood sugar levels. Regular monitoring is advised.
- **Fluid Retention:** Progesterone may cause fluid retention, particularly in patients with pre-existing kidney or heart conditions.
- **Pregnancy and Lactation:** While progesterone is often used to support early pregnancy, it should not be used in the absence of medical supervision. It is considered safe for use in pregnancy, but should only be used under healthcare supervision.

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#### Side Effects

##### Common Side Effects:

- Drowsiness or fatigue
- Headache
- Abdominal discomfort, bloating, or nausea
- Breast tenderness or enlargement
- Weight gain or fluid retention
- Mood swings or irritability
- Spotting or breakthrough bleeding (especially when starting therapy)

##### Serious Side Effects:

- Severe allergic reactions (difficulty breathing, swelling of the face, lips, or throat)
  - Signs of blood clots (leg swelling, pain, redness, shortness of breath)
  - Severe abdominal pain or yellowing of the skin (possible liver issues)
  - Vision problems or severe headaches (possible signs of increased intracranial pressure)
  - Unusual vaginal bleeding
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## Drug Interactions

Progesterone may interact with various medications, including:

- **Anticoagulants:** Progesterone may increase the risk of bleeding when used with blood thinners.
  - **Corticosteroids:** Concurrent use with corticosteroids may enhance their effects.
  - **Antiepileptics and Anticonvulsants:** Certain anti-seizure medications may decrease the effectiveness of progesterone.
  - **Estrogen:** When used in combination with estrogen in hormone replacement therapy, progesterone may help balance the effects of estrogen on the uterus.
  - **Antibiotics:** Certain antibiotics may interfere with the metabolism of progesterone.
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## Storage Instructions

- **Temperature:** Store at room temperature (15°C to 30°C).
  - **Protection:** Keep the softgel capsules in their original container and away from moisture and direct sunlight.
  - **Shelf Life:** Do not use after the expiration date indicated on the packaging.
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## Presentation

- **Form:** Softgel capsule
- **Strength:** 100mg 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) 100mg Softgel is an effective and bioavailable form of progesterone used for treating hormone imbalances, supporting pregnancy, and managing various menstrual disorders. Its natural composition makes it a preferred choice for many patients undergoing hormone therapy. As with all medications, it should be used under the supervision of a healthcare provider, with appropriate monitoring for potential side effects and contraindications.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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

Panchkula-134113

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