

# Peblegest 200 Injection

## Product Information: Progesterone I.P. 200 Injection

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### Composition:

#### Each vial contains:

- **Progesterone I.P.: 200 mg in 1 mL of solution.**
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### Pharmacological Class:

- **Progesterone: Progestogen** (a synthetic form of the naturally occurring hormone progesterone), used in hormone replacement therapy (HRT) and in the management of various gynecological conditions.
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### Indications:

**Progesterone I.P. 200 Injection** is used for the following indications:

1. **Hormone Replacement Therapy (HRT):** In women with insufficient natural progesterone production, typically for the treatment of symptoms associated with menopause (such as hot flashes, vaginal dryness, and mood disturbances) when combined with estrogen therapy.
2. **Support in Assisted Reproductive Technologies (ART):** For women undergoing in vitro fertilization (IVF) or other fertility treatments, to support the luteal phase (the second half of the

menstrual cycle) after ovulation, or to support early pregnancy.

3. **Endometrial Disorders:** Treatment of conditions such as endometrial hyperplasia (thickening of the uterine lining) and abnormal uterine bleeding due to hormonal imbalances.
  4. **Prevention of Preterm Birth:** In certain high-risk pregnancies, progesterone injections may be prescribed to reduce the risk of preterm labor.
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### Mechanism of Action:

**Progesterone** is a naturally occurring steroid hormone that plays a key role in the regulation of the menstrual cycle and pregnancy. It works by:

- **Inhibiting the secretion of luteinizing hormone (LH)**, thereby preventing ovulation.
  - **Inducing endometrial changes** in preparation for implantation of a fertilized egg and maintaining early pregnancy.
  - **Reducing uterine contractility**, which helps in preventing early miscarriage and preterm labor.
  - **Regulating menstrual cycles** and preventing abnormal uterine bleeding in women with hormonal imbalances.
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### Dosage and Administration:

**Progesterone I.P. 200 Injection** is administered by intramuscular (IM) injection only. The

**dosage and frequency depend on the condition being treated:**

- **For Assisted Reproductive Technologies (ART):**
  - **Luteal Phase Support:** 200 mg to 400 mg, given once or twice daily, starting on the day of embryo transfer and continuing until the 10th week of pregnancy, or as directed by the healthcare provider.
- **For Hormone Replacement Therapy (HRT):**
  - The typical dosage is 200 mg to 300 mg IM injection, administered for 10-12 days, usually following estrogen therapy. Treatment may continue as part of an ongoing HRT regimen.
- **For Prevention of Preterm Birth:**
  - Progesterone I.P. 200 mg is typically administered once a week starting from the 16th week of pregnancy until 36 weeks.
- **For Endometrial Disorders:**
  - Dosages may vary depending on the specific condition and treatment regimen prescribed by a doctor.

**Injection Site:** Administer the injection deep into the gluteal muscle (upper outer quadrant) to reduce the risk of irritation and ensure proper absorption.

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#### **Contraindications:**

- Hypersensitivity to progesterone or any component of the formulation.
- History of thromboembolic disorders (e.g., deep vein thrombosis, pulmonary embolism).
- Severe liver dysfunction or liver disease (such as cirrhosis or liver tumors).

- Undiagnosed vaginal bleeding, unless caused by a known condition such as a hormonal imbalance or abnormal uterine bleeding.
  - Active or history of breast cancer or other progesterone-sensitive cancers.
  - Pregnancy (when used for non-pregnancy related indications).
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#### **Warnings and Precautions:**

- **Thromboembolic Risk:** Progesterone has been associated with an increased risk of blood clot formation. Patients with a history of blood clots or those who are at high risk (e.g., smoking, obesity, immobility) should use with caution.
  - **Endometrial Cancer:** Use of progesterone without estrogen in women with a uterus may increase the risk of endometrial cancer.
  - **Breast Cancer Risk:** Hormonal treatments, including progesterone, may slightly increase the risk of breast cancer in some women.
  - **Liver Function:** Patients with liver disorders should be monitored regularly, as progesterone is metabolized in the liver.
  - **Pregnancy and Lactation:** Progesterone should only be used during pregnancy when clearly indicated (e.g., luteal phase support or prevention of preterm birth). It is excreted in breast milk; use with caution during breastfeeding.
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#### **Adverse Effects:**

- **Common Side Effects:**
  - Pain or swelling at the injection site.
  - Headache or dizziness.
  - Fatigue or drowsiness.

- Nausea, bloating, or abdominal discomfort.
  - Irregular menstrual bleeding or spotting.
  - **Serious Side Effects (rare):**
    - Thromboembolic events (deep vein thrombosis, pulmonary embolism, stroke).
    - Severe allergic reactions (anaphylaxis, rash, swelling of the face or throat).
    - Breast tenderness or enlargement.
    - Depression, mood swings, or changes in mood.
    - Liver problems, signs include yellowing of the skin or eyes, dark urine, and stomach pain.
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#### **Drug Interactions:**

- **Other Hormonal Medications:** Progesterone may interact with other hormonal therapies, including oral contraceptives and estrogen. The risk of side effects may increase if used with other hormonal treatments.
  - **Anticonvulsants (e.g., phenytoin, carbamazepine):** May reduce the effectiveness of progesterone.
  - **CYP450 Enzyme Inhibitors (e.g., ketoconazole, rifampin):** These can alter progesterone metabolism, potentially altering its effects.
  - **Anticoagulants:** Use caution when combined with anticoagulant medications, as progesterone may influence blood clotting mechanisms.
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#### **Use in Special Populations:**

- **Pregnancy: Progesterone I.P. 200 Injection** is used during pregnancy in specific cases such as luteal phase

- support in ART and prevention of preterm birth. Its use should be supervised by a healthcare provider.
  - **Lactation:** Progesterone is excreted in breast milk, but no significant adverse effects have been noted. It should only be used during lactation when necessary and prescribed by a doctor.
  - **Elderly:** No specific dosage adjustments are recommended for elderly patients, but they should be monitored for any adverse effects, especially related to the cardiovascular system.
  - **Renal and Hepatic Impairment:** Caution should be used in patients with renal or hepatic conditions. Regular monitoring may be necessary.
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#### **Storage:**

- Store at room temperature (15-30°C), away from direct heat and moisture.
  - Do not refrigerate or freeze the product.
  - Protect from light and keep the vial tightly sealed when not in use.
  - Keep out of the reach of children.
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#### **Packaging:**

- Available in single-dose vials containing 200 mg of Progesterone I.P. in 1 mL of solution.
  - Typically packaged in a box containing 1 vial or 5 vials, with accompanying instructions for use.
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#### **Patient Instructions:**

1. **Injection Technique:** This injection should be administered by a healthcare provider or under their supervision.

**Ensure the injection is given deep into the gluteal muscle (upper outer quadrant) to reduce pain and irritation.**

- 2. Missed Dose: If a dose is missed, consult with your healthcare provider to reschedule the missed injection. Do not double the dose.**
  - 3. Side Effect Monitoring: Monitor for any signs of side effects, especially allergic reactions, blood clot symptoms, or liver dysfunction. Contact your healthcare provider if any adverse symptoms occur.**
  - 4. Regular Follow-ups: Ensure regular follow-up appointments with your healthcare provider to monitor the effectiveness and safety of the treatment.**
  - 5. Disposal: Safely dispose of needles and syringes after use, as per local regulations.**
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**Progesterone I.P. 200 Injection is a critical treatment in supporting various gynecological conditions, fertility treatments, and preventing preterm labor. It is important to use this medication under proper medical supervision to ensure safety and maximize its therapeutic benefits.**

Manufactured in India for:



**Cafoli Lifecare Pvt. Ltd.**

**(An ISO 9001: 2015 Certified Co.)**

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