

Peblegest 100 Injection

Progesterone I.P. 100mg Injection

Description

Progesterone I.P. 100mg Injection is a synthetic form of the naturally occurring female hormone progesterone. It is commonly used in hormone replacement therapy (HRT), fertility treatments, and to support pregnancy in certain cases. This injection provides the necessary progesterone that supports the implantation of a fertilized egg in the uterus and helps maintain pregnancy. It is typically prescribed when there is a deficiency or low level of progesterone in the body.

Composition

Each vial of Progesterone I.P. 100mg Injection contains:

- **Progesterone (I.P.) – 100mg**
 - **Excipients:** The injection contains suitable excipients such as sesame oil or other stabilizing agents as per the formulation.
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Pharmacological Action

Progesterone is a key hormone in the menstrual cycle and early stages of pregnancy. It plays an essential role in:

- **Supporting the Luteal Phase:** After ovulation, progesterone prepares the uterine lining for the implantation of a fertilized egg.
- **Regulating the Menstrual Cycle:** Progesterone helps to regulate menstruation and maintain the uterine environment suitable for pregnancy.

- **Maintaining Pregnancy:** It helps maintain the uterine lining during pregnancy, preventing spontaneous abortion and supporting fetal development.
 - **Modifying the Immune System:** Progesterone has immune-modulating effects, which are particularly important during pregnancy to avoid rejection of the embryo.
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Indications

Progesterone I.P. 100mg Injection is indicated for the following conditions:

1. **Assisted Reproductive Technology (ART):** Used in fertility treatments such as in vitro fertilization (IVF) to support the luteal phase and pregnancy.
 2. **Progesterone Deficiency:** For women with insufficient progesterone production during the luteal phase, which can lead to conditions like luteal phase defect or irregular menstrual cycles.
 3. **Threatened or Recurrent Miscarriage:** Progesterone is used to help maintain pregnancy and prevent early miscarriage in cases where progesterone deficiency is suspected.
 4. **Hormone Replacement Therapy (HRT):** Used in combination with estrogen in menopausal women to help prevent endometrial hyperplasia caused by unopposed estrogen therapy.
 5. **Dysfunctional Uterine Bleeding:** Used to help regulate abnormal menstrual bleeding caused by hormonal imbalance.
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Dosage and Administration

Recommended Dosage:

- **For Fertility and Assisted Reproductive Technology (ART):**
The usual dose is 1 injection of 100mg of progesterone administered intramuscularly daily or as prescribed by the physician. The dosage may vary based on individual patient response and the specific ART protocol.
- **For Support in Early Pregnancy (Threatened Miscarriage):**
The dosage may vary depending on the stage of pregnancy. Commonly, 100mg is administered 1-2 times daily until the pregnancy stabilizes or as directed by the healthcare provider.
- **For Hormone Replacement Therapy (HRT):**
100mg of progesterone may be given 1-2 times a week in combination with estrogen therapy, as directed by the physician.

Administration Method:

- **Route of Administration:** Intramuscular (IM) injection.
- **Injection Site:** The injection should be administered in the gluteal muscle (buttocks), preferably in the upper outer quadrant.
- **Technique:** The injection should be given deep into the muscle. Care should be taken to avoid injecting into blood vessels, and proper aseptic technique should be followed during the injection process.

Contraindications

Progesterone I.P. 100mg Injection is contraindicated in the following conditions:

- Hypersensitivity to progesterone or any of the excipients in the formulation.
- Severe liver disease (such as cirrhosis or liver tumors).
- Breast cancer or other hormone-dependent tumors.
- Unexplained vaginal bleeding (unless under a doctor's supervision).

- History of or current deep vein thrombosis (DVT), pulmonary embolism, or other thromboembolic disorders.
- Active arterial disease (such as stroke, coronary artery disease, or heart attack).
- Pregnancy-related conditions such as ectopic pregnancy or molar pregnancy.

Warnings and Precautions

- **Risk of Blood Clots:** Patients with a history of blood clots or a family history of thrombosis should use this medication with caution, as progesterone has been associated with an increased risk of blood clot formation.
- **Pregnancy:** Progesterone is used during pregnancy in certain cases to maintain a healthy pregnancy. However, it should not be used for non-pregnant women without a clear medical indication.
- **Liver Function:** Regular monitoring of liver function is advised for patients using this medication for prolonged periods, especially in those with pre-existing liver conditions.
- **Breast Cancer:** Progesterone should not be used in patients with a history or current diagnosis of breast cancer, as it may stimulate the growth of hormone-sensitive tumors.
- **Depression:** Patients with a history of depression should be monitored closely as progesterone can sometimes affect mood and may exacerbate symptoms of depression.
- **Allergic Reactions:** Signs of severe allergic reactions such as difficulty breathing, swelling of the face or throat, or hives should be treated immediately.
- **Injection Site Reactions:** Pain, redness, or swelling at the injection site may occur. If these symptoms persist or worsen, medical advice should be sought.

Side Effects

Common Side Effects:

- Pain or irritation at the injection site
- Dizziness or drowsiness
- Fatigue or tiredness
- Nausea or vomiting
- Headache
- Breast tenderness or swelling
- Mood swings or irritability

Serious Side Effects:

- Severe allergic reactions (anaphylaxis)
- Deep vein thrombosis (DVT), pulmonary embolism, or other thromboembolic events
- Liver dysfunction (jaundice, dark urine, or yellowing of the skin/eyes)
- Severe headaches or visual disturbances (suggesting a potential problem with intracranial pressure)
- Unusual bleeding or spotting (particularly if you have an underlying condition affecting your blood clotting).

Drug Interactions

Progesterone may interact with several other medications, including:

- **Anticoagulants:** Progesterone can affect blood clotting mechanisms, so patients on anticoagulants (e.g., warfarin) should be monitored carefully.
- **Corticosteroids:** May enhance the effects of corticosteroids, leading to increased side effects.
- **Anti-seizure Medications:** Certain anti-seizure drugs can reduce the effectiveness of progesterone.
- **Other Hormonal Medications:** Concurrent use with estrogen or other hormonal medications should be done under medical supervision, especially in hormone replacement therapy (HRT) settings.

Storage Instructions

- **Temperature:** Store at room temperature (15°C to 30°C).
- **Keep the vials away from direct sunlight and moisture.**
- **Do not freeze the injection.**
- **Keep out of reach of children.**

Presentation

- **Form:** Injection
- **Strength:** Progesterone 100mg
- **Pack Size:** Available in 1 vial per pack or multi-dose vials depending on the manufacturer.

Conclusion

Progesterone I.P. 100mg Injection is a highly effective treatment for conditions related to progesterone deficiency, including hormone replacement therapy and fertility treatments. It provides the necessary support for pregnancy maintenance and helps regulate hormonal balance. However, due to its potential for serious side effects and contraindications, it should only be used under the guidance of a qualified healthcare provider. Regular monitoring and medical oversight are essential for achieving the best therapeutic outcomes while minimizing risks.

Manufactured in India for:

CafoliTM
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Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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