Information For the Use Hydroxyprogesterone (500mg)

Peblegest H 500 Injection

Hydroxyprogesterone (500 mg) Injection

prepare the uterine lining for embryo implantation.

Description:

Hydroxyprogesterone (500 mg) injection is a synthetic progestin used primarily to manage various gynecological and obstetric conditions. It is often prescribed to reduce the risk of preterm labor in women at high risk of delivering prematurely.

Composition:

• Hydroxyprogesterone: 500 mg per 1 ml of injection

Indications:

Hydroxyprogesterone injection is indicated for:

- 1. Prevention of Preterm Labor:
 - For pregnant women at high risk of preterm birth, Hydroxyprogesterone helps to reduce the likelihood of preterm labor and increases the chances of carrying the pregnancy to term.
- 2. Secondary Amenorrhea and Abnormal Uterine Bleeding:
 - Hydroxyprogesterone is used to treat secondary amenorrhea (absence of menstruation).
- **3.** Luteal Phase Support in Assisted Reproductive Technologies (ART):
 - Hydroxyprogesterone is administered in ART procedures, such as in vitro fertilization (IVF), to support the luteal phase and

Mechanism of Action:

Hydroxyprogesterone is a synthetic form of the naturally occurring hormone progesterone. It works by:

- 1. Preventing Uterine Contractions: Hydroxyprogesterone helps to maintain a relaxed state of the uterus, reducing the risk of premature contractions and preterm labor.
- 2. Maintaining Pregnancy: It supports the uterine lining, preventing early miscarriage in certain high-risk pregnancies.
- 3. Regulating the Menstrual Cycle: In women with hormonal imbalances, it helps regulate the menstrual cycle by influencing the endometrial lining and ensuring adequate levels of progesterone.

Dosage and Administration:

- Prevention of Preterm Labor:
 - 500 mg is typically administered once a week by intramuscular injection.
 - Treatment is usually continued until 37 weeks of gestation or as directed by the healthcare provider.
- Secondary Amenorrhea and Abnormal Uterine Bleeding:
 - Dosage may vary, with 500 mg to 1000 mg administered intramuscularly, depending on the

individual case and response to treatment.

- Luteal Phase Support in ART:
 - Dosage and timing of injections are determined by the fertility specialist, typically beginning after ovulation or embryo transfer and continuing for several weeks.

Note:

- The injection should be administered by a healthcare professional to ensure proper technique and minimize side effects.
- The exact dosage and duration of treatment should be followed as prescribed by a healthcare provider.

Side Effects:

- Common:
 - Pain, swelling, or redness at the injection site.
 - Mild abdominal discomfort or bloating.
 - Headache or dizziness and vomiting.
- Serious but Rare:
 - Blood Clotting Disorders: Increased risk of deep vein thrombosis (DVT), pulmonary embolism (PE), or stroke, particularly in women with a history of clotting disorders.
 - Liver Dysfunction: Symptoms such as yellowing of the skin or eyes (jaundice), dark urine, or unexplained fatigue.
 - Mood Changes: Anxiety or depressive symptoms.

Precautions:

1. Blood Clotting Disorders: Use with caution in patients with a history of

blood clots or thromboembolic disorders, as Hydroxyprogesterone may increase the risk of clots.

- 2. Liver Disease: Monitor liver function in patients with pre-existing liver conditions, as Hydroxyprogesterone may exacerbate liver dysfunction.
- 3. Pregnancy and Breastfeeding: Hydroxyprogesterone is generally considered safe for use in pregnancy, especially for the prevention of preterm labor. Consult a doctor before using during breastfeeding.
- 4. Depression and Mental Health: Women with a history of depression or mood disorders should be monitored during treatment.
- 5. Monitoring: Regular monitoring may be needed to assess the effectiveness of treatment and to detect any potential side effects, especially when used over an extended period.

Storage:

- Store Hydroxyprogesterone injection at room temperature (15-30°C), away from direct heat and moisture.
- Do not freeze and Keep the vial tightly closed and out of reach of children.

Note:

Hydroxyprogesterone injection should be used under the supervision of a healthcare provider.

Manufactured in India for:

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