Caprogen™

Hydroxyprogesterone
Caproate USP 250 mg/ml

COMPOSITION

Caprogen™ IM Injection: Hydroxyprogesterone Caproate is a pale yellow color oil base sterile injection which is filled and sealed in 1 ml amber color glass ampoule. Each 1 ml Ampoule contains Hydroxyprogesterone Caproate USP 250 mg.

DESCRIPTION

Caprogen™ (Hydroxyprogesterone caproate) is a synthetic steroid hormone that is similar to medroxyprogesterone acetate and megestrol acetate. It is an ester derivative of 17α-hydroxyprogesterone formed from caproic acid (hexanoic acid).

INDICATIONS

Caprogen™ is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of **Caprogen**™ Injection is based on improvement in the proportion of women who delivered < 37 weeks of gestation.

Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of **Caprogen**™ Injection has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.

DOSAGE AND ADMINISTRATION

Dosage

Administer intramuscularly (IM) at a dose of 250 mg (1 mL) once weekly (every 7 days). Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation.

Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

Administration

1. Draw up 1 mL of drug into a 3 mL syringe.
2. Clean the injection site with an alcohol pad.
3. After preparing the skin, inject in the upper outer quadrant of the gluteus maximus. The solution is viscous and oily. Slow injection (over one minute or longer) is recommended.
4. Applying pressure to the injection site may minimize bruising and swelling.

CONTRAINDICATIONS

- Current thrombosis or thromboembolic disorders or history of these conditions.
- Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions
- Undiagnosed abnormal vaginal bleeding unrelated to pregnancy.
- Cholestatic jaundice of pregnancy
- Liver tumors (benign or malignant) or active liver disease
- Uncontrolled hypertension

WARNING AND PRECAUTIONS

Thromboembolic Disorders: Discontinue **Caprogen**™ if an arterial or deep venous thrombotic or thromboembolic event occurs.

Allergic Reactions: Allergic reactions, including urticaria, pruritus and angioedema, have been reported with use of **Caprogen**™ or with other products containing castor oil. Consider discontinuing the drug if such reactions occur.

Decrease in Glucose Tolerance: A decrease in glucose tolerance has been observed in some patients on progestin treatment. The mechanism of this decrease is not known. Carefully monitor pre-diabetic and diabetic women while they are receiving **Caprogen**™.

Fluid Retention: Because progestational drugs may cause some degree of fluid retention, carefully monitor women with conditions that might be influenced by this effect (e.g., preeclampsia, epilepsy, migraine, asthma, cardiac or renal dysfunction).

Depression: Monitor women who have a history of clinical depression and discontinue **Caprogen**™ if clinical depression recurs.

Jaundice: Carefully monitor women who develop jaundice while receiving **Caprogen**™ and consider whether the benefit of use warrants continuation.

Hypertension: Carefully monitor women who develop hypertension while receiving **Caprogen**™ and consider whether the benefit of use warrants continuation.

SPECIFIC POPULATIONS

Pregnancy: Category B. No adequate and well-controlled studies in women during first trimester of pregnancy. Teratogenic risks to infants following in utero exposure to the drug not demonstrated in a study of pregnant women receiving the drug during their second and third trimesters, as well as in a follow-up safety study of their infants. Not intended to stop active preterm labor; effect of drug for this use unknown.

Lactation: Detectable amounts of progestins identified in breast milk of women receiving progestins. No adverse effects of progestins on breastfeeding performance or on health, growth, or development of infants. Discontinue drug at 37 weeks of gestation or upon delivery.

Pediatric Use: Not indicated for use in pediatric patients. Safety and efficacy not established in pediatric patients <16 years of age. Limited number of women<18 years of age studied; safety and efficacy expected to be the same in women ≥16 years of age compared with those ≥ 18 years of age.

Geriatric Use: Not evaluated in women ≥65 years of age. Not intended for use in postmenopausal women. Safety and efficacy not established in postmenopausal women.

Hepatic Impairment: Contraindicated in patients with liver tumors (benign or malignant) or active liver disease. Effect of hepatic impairment on pharmacokinetics of the drug not evaluated.

Renal Impairment: Effect of renal impairment on pharmacokinetics of the drug not evaluated.

SIDE EFFECTS

Common side events (incidence ≥ 2% and at a higher rate compared to the control group) with hydroxyprogesterone caproate IM were injection site reactions like pain, swelling, pruritus, nodule, urticaria, pruritus, nausea and diarrhea.

OVERDOSAGE

In the case of overdosage, the patient should be treated symptomatically.

STORAGE CONDITION

Store below 30°C. Protect from light. Keep out of reach of children.

COMMERCIAL PACK

Caprogen™ **IM Injection:** Each commercial pack contains 1x1 ampoule of 250 mg/ml Hydroxyprogesterone caproate USP in Alu-PVC blister strip and 1 sterile disposable syringe.

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Manufactured by:
Nuvista Pharma Limited
48 Tongi industrial area, Gazipur, Bangladesh
A subsidiary of Beximco Pharmaceuticals Ltd.