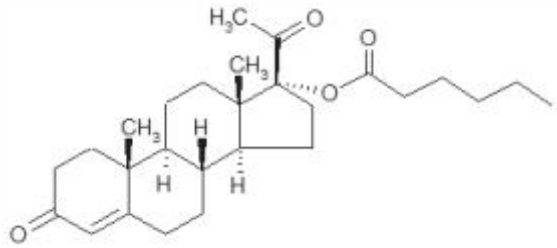
PYXOLUTE

Hydroxyprogesterone Caproate Injection USP

Composition :
Each ml contains :
Hydroxyprogesterone
caproate USP 250 mg
in oily solution

DESCRIPTION
The active pharmaceutical ingredient in hydroxyprogesterone caproate injection is hydroxyprogesterone caproate, a progestin.
The chemical name for hydroxyprogesterone caproate is pregn-4-ene-3,20-dione, 17[(1-oxohexyl)oxy]. It has an empirical formula of C27H40O4 and a molecular weight of 428.60.
Hydroxyprogesterone caproate exists as white to practically white crystals or powder with a melting point of 120° to 124°C.
The structural formula is:



Hydroxyprogesterone caproate injection is a clear, yellow, sterile, non-pyrogenic solution for intramuscular injection. Each 1 mL single-dose vial contains hydroxyprogesterone caproate, 250 mg/mL (25% w/v), in a preservative-free solution containing castor oil (30.6% v/v) and benzyl benzoate (46% v/v).

INDICATIONS AND USAGE
Hydroxyprogesterone caproate injection 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 hydroxyprogesterone caproate injection is based on improvement in the proportion of women who
delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.
Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of hydroxyprogesterone caproate 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
Dosing
- Administer **intramuscularly** at a dose of 250 mg (1 mL) once weekly (every 7 days) in the upper outer quadrant of the gluteus maximus by a healthcare provider
- 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

Preparation and Administration
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
Hydroxyprogesterone caproate injection is a clear, yellow solution. The solution must be clear at the time of use; replace vial if visible particles or crystals are present.
Hydroxyprogesterone caproate injection single-dose vials are only for intramuscular injection with a syringe into the upper outer quadrant of the gluteus maximus, rotating the injection site to the alternate side from the previous week, using the following preparation and administration procedure:
1. Clean the vial top with an alcohol swab before use.
2. Draw up 1 mL of drug into a 3 mL syringe with an 18 gauge needle.
3. Change the needle to a 21 gauge 1½ inch needle.
4. 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.
5. Applying pressure to the injection site may minimize bruising and swelling.

DOSAGE FORMS AND STRENGTHS
Intramuscular injection: 250 mg/mL

CONTRAINDICATIONS
Do not use hydroxyprogesterone caproate injection in women with any of the following conditions:
- Current or history of thrombosis or thromboembolic disorders
- 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

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WARNINGS AND PRECAUTIONS
Thromboembolic Disorders
Discontinue hydroxyprogesterone caproate injection 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 hydroxyprogesterone caproate injection 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 prediabetic and diabetic women while they are receiving hydroxyprogesterone caproate injection.
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 hydroxyprogesterone caproate injection if clinical depression recurs.
Jaundice
Carefully monitor women who develop jaundice while receiving hydroxyprogesterone caproate injection and consider whether the benefit of use warrants continuation.
Hypertension
Carefully monitor women who develop hypertension while receiving hydroxyprogesterone caproate injection and consider whether the benefit of use warrants continuation.

Marketed by:
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