



Patient Information
Hydroxyprogesterone Caproate
Injection USP
(hye-DROX-ee-proe-JES-ter-one
KAP-roe-ate)
vial for intramuscular use

Read this Patient Information leaflet before you receive hydroxyprogesterone caproate injection. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is hydroxyprogesterone caproate injection?

Hydroxyprogesterone caproate injection is a prescription hormone medicine (progestin) used in women who are pregnant and who have delivered a baby too early (preterm) in the past. Hydroxyprogesterone caproate injection is used in these women to help lower the risk of having a preterm baby again. It is not known if hydroxyprogesterone caproate injection reduces the number of babies who are born with serious medical conditions or die shortly after birth. Hydroxyprogesterone caproate injection is for women who:

- Are pregnant with one baby.
- Have had a preterm delivery of one baby in the past.

Hydroxyprogesterone caproate injection is not intended for use to stop active preterm labor. It is not known if hydroxyprogesterone caproate injection is safe and effective in women who have other risk factors for preterm birth. Hydroxyprogesterone caproate injection is not for use in women under 16 years of age.

Who should not receive hydroxyprogesterone caproate injection?

Hydroxyprogesterone caproate injection should not be used if you have:

- blood clots or other blood clotting problems now or in the past
- breast cancer or other hormone-sensitive cancers now or in the past
- unusual vaginal bleeding not related to your current pregnancy

- yellowing of your skin due to liver problems during your pregnancy
- liver problems, including liver tumors
- high blood pressure that is not controlled

What should I tell my healthcare provider before receiving hydroxyprogesterone caproate injection?

Before you receive hydroxyprogesterone caproate injection, tell your healthcare provider about all of your medical conditions, including if you have:

- a history of allergic reaction to hydroxyprogesterone caproate, castor oil, or any of the other ingredients in hydroxyprogesterone caproate injection. See the end of this Patient Information leaflet for a complete list of ingredients in hydroxyprogesterone caproate injection.
- diabetes or pre-diabetes.
- epilepsy (seizures).
- migraine headaches.
- asthma.
- heart problems.
- kidney problems.
- depression.
- high blood pressure.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Hydroxyprogesterone caproate injection may affect the way other medicines work, and other medicines may affect how hydroxyprogesterone caproate injection works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I receive hydroxyprogesterone caproate injection?

- **Do not** give yourself hydroxyprogesterone caproate injection. A healthcare provider will give you the hydroxyprogesterone caproate injection 1 time each week (every 7 days) in the upper outer area of the buttocks as an injection into the muscle (intramuscular).
- You will start receiving hydroxyprogesterone caproate injection anytime from 16 weeks and 0 days of your pregnancy, up to

20 weeks and 6 days of your pregnancy.

- You will continue to receive hydroxyprogesterone caproate injection 1 time each week until week 37 (through 36 weeks and 6 days) of your pregnancy or when your baby is delivered, whichever comes first.

What are the possible side effects of hydroxyprogesterone caproate injection?

Hydroxyprogesterone caproate injection may cause serious side effects, including:

- **Blood clots.** Symptoms of a blood clot may include:
 - o leg swelling
 - o redness in your leg
 - o a spot on your leg that is warm to the touch
 - o leg pain that gets worse when you bend your foot

Call your healthcare provider right away if you get any of the symptoms above during treatment with hydroxyprogesterone caproate injection.

- **Allergic reactions.** Symptoms of an allergic reaction may include:
 - o hives
 - o itching
 - o swelling of the face

Call your healthcare provider right away if you get any of the symptoms above during treatment with hydroxyprogesterone caproate injection.

- **Decrease in glucose (blood sugar) tolerance.** Your healthcare provider will need to monitor your blood sugar while taking hydroxyprogesterone caproate injection if you have diabetes or pre-diabetes.
- **Your body may hold too much fluid (fluid retention).**
- **Depression.**
- **Yellowing of your skin and the whites of your eyes (jaundice).**
- **High blood pressure.**

The most common side effects of hydroxyprogesterone caproate injection include:

- pain, swelling, itching or a hard bump at the injection site
- hives
- itching
- nausea
- diarrhea



Call your healthcare provider if you have the following at your injection site:

- increased pain over time
- oozing of blood or fluid
- swelling

Other side effects that may happen more often in women who receive hydroxyprogesterone caproate injection include:

- Miscarriage (pregnancy loss before 20 weeks of pregnancy)
- Stillbirth (fetal death occurring during or after the 20th week of pregnancy)
- Hospital admission for preterm labor
- Preeclampsia (high blood pressure and too much protein in your urine)
- Gestational hypertension (high blood pressure caused by pregnancy)
- Gestational diabetes
- Oligohydramnios (low amniotic fluid levels)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of hydroxyprogesterone caproate injection. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store hydroxyprogesterone caproate injection?

- **Hydroxyprogesterone caproate injection vial for intramuscular use:**
 - o Store the vial at room temperature between 68°F to 77°F (20°C to 25°C).
 - o Do not refrigerate or freeze.
 - o Protect the vial from light.
 - o Store the vial in its box in an upright position.

Keep hydroxyprogesterone caproate injection and all medicines out of the reach of children.

General information about the safe and effective use hydroxyprogesterone caproate injection.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use hydroxyprogesterone caproate injection for a condition for which it was not prescribed. Do not give hydroxyprogesterone caproate injection to other people, even if they have the same symptoms you have. It may harm them.


This leaflet summarizes the most important information about hydroxyprogesterone caproate injection. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about hydroxyprogesterone caproate injection that is written for health professionals.

What are the ingredients in hydroxyprogesterone caproate injection?

Active ingredient: hydroxyprogesterone caproate
Inactive ingredients: castor oil, benzyl benzoate, and benzyl alcohol (a preservative)

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For more information, call 1-800-818-4555.

This Patient Information has been approved by the U.S. Food and Drug Administration