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2. Hydroxyprogesterone

# Hydroxyprogesterone injection

**Generic name:** hydroxyprogesterone injection [ hye-DROX-ee-pro-JES-te-rone ]

Brand names: Makena, Makena Auto-Injector, Hylutin, Delta-Lutin, Duralutin, Hyprogesterone, Prodrox

Dosage forms: intramuscular solution (250 mg/mL), subcutaneous solution (275 mg/1.1 mL)

**Drug class: Progestins** 



Medically reviewed by Drugs.com on Jun 18, 2024. Written by Cerner Multum.

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## What is hydroxyprogesterone?

Hydroxyprogesterone is a form of progestin, a manmade form of a female hormone called progesterone.

Hydroxyprogesterone is used to lower the risk of premature birth in a woman who has already had one premature baby. Hydroxyprogesterone will not stop premature labor that has already begun.

Hydroxyprogesterone is not for use in women who are pregnant with more than one baby (twins, triplets, etc).

Hydroxyprogesterone may also be used for purposes not listed in this medication guide.

## Hydroxyprogesterone side effects

Get emergency medical help if you have **signs of an allergic reaction:** hives, itching; difficulty breathing; swelling of your face, lips, tongue, or throat.

Hydroxyprogesterone injection may cause serious side effects. Call your doctor at once if you have:

- swelling, oozing, bleeding, or worsening pain where the injection was given;
- jaundice (yellowing of the skin or eyes);
- symptoms of depression (sleep problems, weakness, mood changes);
- swelling in your hands, ankles, or feet;
- increased blood pressure--severe headache, blurred vision, pounding in your neck or ears, anxiety, nosebleed; or
- signs of a blood clot--sudden numbness or weakness, problems with vision or speech, swelling or redness in an arm or leg.

## Common side effects of hydroxyprogesterone injection may include:

pain, swelling, itching, rash, or a lump where the medicine was injected;

- nausea; or
- diarrhea.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

1 Hydroxyprogesterone side effects (more detail)

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You should not use hydroxyprogesterone injection if you have: uncontrolled high blood pressure, unusual vaginal bleeding, liver disease or liver cancer, jaundice caused by your pregnancy, or if you have ever had circulation problems, a stroke or blood clot, or cancer of the breast, uterus/cervix, or vagina.

## Before taking this medicine

You should not be treated with this medicine if you are allergic to hydroxyprogesterone or castor oil, or if you have:

- unusual vaginal bleeding that is not related to your pregnancy;
- severe or uncontrolled high blood pressure;
- liver disease or liver cancer;
- jaundice caused by your pregnancy;
- a history of cancer of the breast, uterus/cervix, or vagina; or
- a history of a stroke, blood clot, or circulation problems.

Hydroxyprogesterone is not approved for use by anyone younger than 16 years old.

Tell your doctor if you have ever had:

- eclampsia or preeclampsia of pregnancy;
- · kidney disease;
- high blood pressure, heart disease;
- migraine headaches;
- diabetes (in you or a family member);
- epilepsy or other seizure disorder;
- asthma; or
- · depression.

It is not known whether hydroxyprogesterone will prevent any medical problems in a newborn baby. Talk to your doctor about your baby's individual risk.

# How is hydroxyprogesterone given?

Hydroxyprogesterone is injected under the skin or into a muscle.

A healthcare provider will give you this injection.

The first hydroxyprogesterone injection is usually given during the second trimester of pregnancy. The usual dosing schedule is one injection per week until the 37th week or until your baby is born. Follow your doctor's instructions.

Your doctor will need to check your progress on a regular basis. **Do not miss any scheduled appointments.** Every woman should remain under the care of a doctor during pregnancy.

## Hydroxyprogesterone injection dosing information

#### **Usual Adult Dose for Premature Labor:**

Treatment should begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation:

Intramuscularly (IM): 250 mg IM once every 7 day in the upper outer quadrant of the gluteus maximus

Subcutaneously: 275 mg subcutaneously once every 7 days in the back of either upper arm

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

#### Comments:

-Efficacy of this drug 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.

Use: To reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

#### **Usual Pediatric Dose for Premature Labor:**

16 years or older:

Treatment should begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation:

Intramuscularly (IM): 250 mg IM once every 7 day in the upper outer quadrant of the gluteus maximus

Subcutaneously: 275 mg subcutaneously once every 7 days in the back of either upper arm

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

#### Comments:

-Efficacy of this drug 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.

Use: To reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

Detailed Hydroxyprogesterone dosage information

## What happens if I miss a dose?

Call your doctor for instructions if you miss an appointment for your hydroxyprogesterone injection.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What should I avoid while receiving hydroxyprogesterone?

Follow your doctor's instructions about any restrictions on food, beverages, or activity.

## What other drugs will affect hydroxyprogesterone?

Other drugs may affect hydroxyprogesterone, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

Hydroxyprogesterone drug interactions (more detail)

## Does hydroxyprogesterone interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

hydroxyprogesterone
+
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## **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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#### **DRUG STATUS**

**Availability** 

Rx Prescription only

**Pregnancy & Lactation** 

& Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

**Approval History** 

□ Drug history at FDA

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6.8 / 10

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