



## Hydroxyurea

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### **IMPORTANT WARNING:**

Hydroxyurea may cause severe, life-threatening side effects, including a low blood count (decrease in the number of blood cells in your body) Tell your doctor if you have or have ever had a blood disease. Tell your doctor and pharmacist about all the medications you are taking. If you take hydroxyurea with other medications that may cause a low blood count, the side effects of the medications may be more severe. If you experience any of the following symptoms, call your doctor immediately: fever, sore throat, chills, cough, and other signs of infection; excessive tiredness; weakness; pale skin; dizziness; confusion; fast heartbeat, shortness of breath; difficulty falling asleep or staying asleep; or unusual bleeding or bruising.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests on a regular basis to check your body's response to hydroxyurea and to see if your blood count has dropped. Your doctor may need to change your dose or tell you to stop taking hydroxyurea for a period of time to allow your blood count to return to normal if it has dropped too low. Follow your doctor's directions carefully and ask your doctor if you do not know how much hydroxyurea you should take.

Taking hydroxyurea may increase the risk that you will develop cancer. This risk may be greater if you take hydroxyurea for a long time.

Talk to your doctor about the risks of taking hydroxyurea.

Women who are taking hydroxyurea, or whose male partners are taking hydroxyurea, may be less likely to become pregnant than women who are not taking hydroxyurea or whose partners are not taking the medication. However, you should not assume that you or your partner cannot become pregnant during your treatment. Tell your doctor if you are pregnant or plan to become pregnant. Use a reliable method of birth control to prevent pregnancy while you are taking hydroxyurea. If you become pregnant while taking hydroxyurea, call your doctor immediately. Hydroxyurea may cause harm or death to the fetus.

### **About your treatment**

Your doctor has ordered hydroxyurea to help treat your illness. Hydroxyurea comes as a capsule to take by mouth.

This medication is used:

- to treat melanoma (a type of skin cancer)
- to treat chronic myelocytic leukemia (CML; cancer of the white blood cells)
- to treat recurrent, metastatic, or inoperable ovarian cancer [cancer of the ovary (a female reproductive organ) that has returned after treatment, that has spread, or that cannot be treated with surgery]
- with radiation therapy to control primary squamous cell carcinoma (a type of skin cancer) that affects any part of the head or neck except the lips
- to prevent crises (episodes of severe pain) and decrease the need for blood transfusions (transfer of one person's blood to another person's body) in people who have sickle cell anemia (a blood disease that may cause painful crises, a low number of red blood cells, infection, and damage to the internal organs).

Hydroxyurea is in a class of medications known as antineoplastic agents. Hydroxyurea treats cancer by slowing or stopping the growth of cancer cells. Hydroxyurea treats sickle cell anemia by changing red blood cells so that they are less likely to bend in an abnormal shape. The length of treatment depends on the condition you have and how well your body responds to this medication.

Hydroxyurea is usually taken once a day. When hydroxyurea is used to treat certain types of cancer, it may be taken once every third day. Try to take hydroxyurea at about the same time of day on the days that you are scheduled to take the medication. Follow the directions on your prescription label carefully and ask your doctor or pharmacist to explain anything you do not understand. Take hydroxyurea exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor may start you on a low dose of hydroxyurea and gradually increase your dose.

Hydroxyurea may help control the symptoms of sickle cell anemia but does not cure the condition. Continue to take hydroxyurea even if you feel well. Do not stop taking this medication without talking to your doctor.

If you forget to take a dose of hydroxyurea, take the missed dose as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed dose and do not take more than one dose in one day. Call your doctor if you miss more than one dose of hydroxyurea.

### ***Other uses for this medicine***

Hydroxyurea is also sometimes used to treat polycythemia vera (a condition in which the body produces too many blood cells), psoriasis (a skin disease in which red, scaly patches form on some areas of the body), and hypereosinophilic syndrome (a condition in which the body produces too many of a certain type of white blood cell). Talk to your doctor about the possible risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

### ***Precautions***

Before taking hydroxyurea,

- tell your doctor and pharmacist if you are allergic to hydroxyurea, any other medications, or any of the inactive ingredients in hydroxyurea capsules. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you are taking or have ever taken an interferon. (Interferons are a group of medications similar to substances produced by the body. They are used to treat diseases that involve the immune system such as certain types of cancer, hepatitis, multiple sclerosis, and genital warts. Brand names include Actimmune, Avonex, Betaseron, Rebif and others.) If you are taking or have ever taken an interferon, there is a greater chance that you will develop severe skin problems during your treatment with hydroxyurea. Ask your doctor or pharmacist if you are not sure if you are taking or have ever taken an interferon.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: medications to treat human

immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS), especially didanosine (Videx) and stavudine (Zerit); probenecid; or sulfinpyrazone (Anturane). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you have human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS), if you are being treated with or have ever been treated with radiation therapy or cancer chemotherapy; if you have or have ever had kidney, or liver disease.
- tell your doctor if you are breast-feeding. You should not breastfeed during your treatment with hydroxyurea.
- your doctor may prescribe a folic acid supplement for you to take during your treatment with hydroxyurea. Take this medication exactly as directed.
- you should know that hydroxyurea may be harmful if it gets on the skin. People who are not taking hydroxyurea should avoid touching hydroxyurea capsules or the bottle that contains the capsules. Always wear disposable gloves when handling hydroxyurea capsules or bottles containing hydroxyurea capsules and wash your hands before and after you touch the bottle or capsules. If the powder from a capsule spills, wipe it up immediately with a damp disposable towel, place the towel in a closed container, such as a plastic bag and throw it away in a trash can that is out of the reach of children and pets.

## ***Side effects***

Hydroxyurea may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- diarrhea
- constipation
- drowsiness

Some side effects can be serious. If you experience any of the following symptoms, or those listed in the IMPORTANT WARNING section, call your doctor immediately.

- rash
- purple, blue, or black discoloration of the skin or nails
- loss of feeling in one area of the body
- sores on the skin or in the mouth
- foul-smelling substance oozing from the skin.
- swelling of the hands, feet, ankles, or lower legs

Hydroxyurea may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

## ***Storage conditions***

Keep hydroxyurea in the container it came in, tightly closed and out of reach of children and pets. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your doctor or pharmacist about the proper disposal of your medication.

## ***In case of emergency/overdose***

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- violet discoloration, swelling, and soreness of the palms and soles
- scaling of the skin on the hands and feet
- darkening of the skin
- sores in the mouth

## ***Special instructions***

- Do not let anyone else take your medication. Ask your pharmacist if you have any questions about refilling your prescription.

## ***Brand names***

- Droxia®
- Hydrea®

## ***Other names***

- Hydroxycarbamide

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