

CONSUMER INFORMATION

HYDREA® (hydroxyurea capsules, USP)

This leaflet is a summary and will not tell you everything about HYDREA®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

HYDREA is used in combination with radiation to treat cancer of the head and neck, not including the lips. It is also used to treat a type of blood cancer that no longer responds to previous treatments. This type of cancer is called resistant chronic myelocytic leukemia.

What it does:

HYDREA seems to interfere with the growth of cancer cells by preventing them from dividing.

When it should not be used:

HYDREA should not be used if:

- you have problems with your bone marrow (low blood count e.g. severe anemia)
- you are sensitive/allergic to hydroxyurea or any other component of this medication. Tell your doctor if you think you have had an allergic reaction to any of these ingredients.

What the medicinal ingredient is:

Hydroxyurea.

What the important nonmedicinal ingredients are:

Citric acid, dibasic sodium phosphate, lactose and magnesium stearate.

What dosage forms it comes in:

HYDREA is available in capsules containing 500 mg hydroxyurea.

WARNINGS AND PRECAUTIONS

BEFORE you use HYDREA talk to your doctor or pharmacist if:

- you have problems with your kidneys. This is because the dose of HYDREA may need to be adjusted.
- you have received radiation therapy. This is because your chances of developing redness of the skin are higher if HYDREA is used with radiation treatment.
- you have HIV/AIDS and are receiving treatment. This can increase your chances of developing:
 - pancreatitis (inflammation of the pancreas)

- and liver problems, or
 - peripheral neuropathy (pins and needles in your hands and feet).
- you are lactose intolerant. This is because HYDREA contains lactose.
- you recently received or are planning to receive a vaccination. Patients taking HYDREA should not receive live vaccines.
- you are receiving treatment with interferon. Inflammation of the blood vessels of the skin, sometimes causing ulcers or death of the blood vessels has been reported. This is most common in patients who have received or are also receiving interferon treatment.
- Female patients:
 - If you are pregnant or planning to become pregnant, there are specific risk you must discuss with your doctor.
 - Avoid becoming pregnant while taking HYDREA. It may harm your unborn child.
 - If you do become pregnant while taking HYDREA, tell your doctor right away.
 - HYDREA can pass into your breastmilk and harm your baby. Do not breastfeed while you are taking HYDREA.
- Male patients who want to father a child:
 - HYDREA may affect your fertility by causing an absence or low number of sperm in your semen. These effects may or may not return to normal. Damage to the genetic material (DNA) in your sperm is also possible.
 - If you want to have a child, talk to your doctor about preserving some semen prior to your treatment with HYDREA.
 - Avoid fathering a child during treatment. Use effective methods of birth control during your treatment with HYDREA and for at least one year after your last dose.
- Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to HYDREA. If you feel drowsy, dizzy weak or tired, do not drive or use tools or machines.
- Tumour Lysis Syndrome (TLS): This side effect can be caused by HYDREA. It is a complication of the breakdown of cancer cells. It is serious and can lead to death. Your doctor will monitor you for signs of TLS.
- A group of disorders that inflame or scar the lung tissue have occurred in patients taking HYDREA. This is called interstitial lung disease (ILD). Your doctor will monitor you for signs of ILD. These include fever, cough, shortness of breath and other respiratory symptoms.
- Hydroxyurea, the active ingredient in HYDREA, may cause cancer and damage to the genetic

material in cells (DNA).

INTERACTIONS WITH THIS MEDICATION

Make sure you talk to your doctor about all medications you are taking, including prescription, non-prescription, and herbal and/or natural products.

The following may interact with HYDREA:

- Cytarabine, a chemotherapy drug used to treat some cancers.
- Medicines used to treat gout.
- Medicines that can affect your blood. This is because using HYDREA at the same time as these medicines will increase your risk for side effects including low blood counts.

PROPER USE OF THIS MEDICATION

While you are using this medicine, your doctor may want you to drink extra fluids so that you will pass more urine. This will help prevent kidney problems and keep your kidneys working well.

Usual dose:

The dose of HYDREA will be different for different patients. The dose you are to take will depend on what this medicine is being used to treat, your weight, and whether or not you are also taking other medicines.

Depending on your condition, the usual dose could be 80 mg/kg, or 20-30 mg/kg given by mouth. How often you take HYDREA will also depend on the type of disease you have.

Take HYDREA exactly as your doctor has indicated.

If you cannot swallow the HYDREA capsules, your healthcare professional can provide you with instructions on another way to take this medicine.

Your doctor may interrupt, change your dose or stop your treatment. This will depend on your disease, how you are feeling and the type of side effects you experience.

Overdose:

If you think you have taken too much HYDREA, contact your doctor, nurse, pharmacist, hospital emergency department or regional poison control immediately, even if there are no symptoms.

The following side effects have been reported in patients who have taken higher doses of HYDREA:

- infections of the skin and mucous membranes (inside the mouth, genitals, skinfolds)

- soreness, redness, swelling and peeling of skin on the palms and soles of feet
- changes in the colour of the skin
- mouth sores

Missed Dose:

If you miss a dose of this medicine check with your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, HYDREA can cause side effects. These are not all the possible side effects that may be experienced when taking HYDREA. If you experience any side effects including some that are not listed here, contact your doctor.

- Rash, redness and ulceration in the face, skin or extremities.
- Skin or nail changes.
- Muscle aches and a general, unwell feeling or malaise.
- Fatigue.

Tell your doctor immediately if you have a high fever ($\geq 39^{\circ}\text{C}$) within 6 weeks of taking HYDREA. The high fever can sometimes come with stomach, lung, muscle, liver, skin or heart problems.

HYDREA can cause abnormal blood test results. Your doctor will decide when to perform blood tests. Your doctor will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Common			
Stomatitis (inflammation in or around the mouth): mouth sores, redness and swelling of the lining of the mouth	X		
Nausea	X		
Vomiting	X		
Diarrhea	X		
Constipation	X		

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Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Cholestasis (decrease in flow of bile from the liver): dark urine, clay-colored or white stools, itchiness, nausea, vomiting, inability to digest certain foods, pain in right upper part of the abdomen, yellow skin or eyes			X
Hepatitis (inflammation of the liver): yellowing of the skin and eyes, feeling tired, stomach ache, fever, nausea, diarrhea, no appetite, fever, headaches			X
Uncommon			
Loss of appetite	X		
Joint pain		X	
Drowsiness: feeling abnormally sleepy or tired during the day	X		
Headache: pain and discomfort in the head, scalp, or neck	X		
Dizziness: feeling faint, woozy, weak or unsteady	X		
Disorientation: losing sense of orientation, may not know their location and identity, or the time and date		X	
Convulsions: sudden, violent, irregular movement of the body		X	
Hallucinations: seeing, feeling or hearing things that are not real		X	
Kidney problems: Bloody or discolored urine, or increase in frequency of urination and pain in the sides where the kidneys are located		X	
Rare			

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	Only if severe	In all cases	
Diffuse pulmonary infiltrates/ fibrosis (when substances thicker than air, like pus, blood, or protein, remain in the lungs): dry painful cough, fever, difficulty breathing, fast shallow breathing			X
Dyspnea (shortness of breath): intense tightening in the chest, difficulty breathing, feeling of suffocation			X
Tumor lysis syndrome (the sudden, rapid death of cancer cells due to the treatment): lack of urination, severe muscle weakness, abnormal heartbeat, seizures			X
Cutaneous vasculitis (inflammation of blood vessels of the skin): skin redness/purple coloration, tiny colored spots, sores, and/or ulcers, sometimes with joint pain and/or fever, death, if you have been or are currently being treated with interferon.		X	
Unknown			
Interstitial lung disease (disorders that inflame or scar the lung tissue): shortness of breath when at rest, which gets worse with exertion; dry cough			X
Systemic lupus (condition that occurs when your body's immune system attacks your own tissues and organs): fever, joint pain, muscle pain; pain when breathing, sharp chest pain, bruising, tender red lumps usually on the shins, itchy red skin when exposed to light		X	

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Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Cutaneous lupus (a form of systemic lupus that only affects the skin): scaly ring-like rash (redness with clear center), red patches on the skin, sensitivity to sunlight, rash on the face usually on cheeks and bridge of nose, ulcers in the mouth		X	

This leaflet was prepared by Bristol Myers Squibb Canada Co., Montréal, Canada H4S 0A4

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HYDREA is a registered of Bristol-Myers Squibb Canada Co.

This is not a complete list of side effects. For any unexpected effects while taking HYDREA, contact your doctor or pharmacist.

HOW TO STORE IT

Store HYDREA at 15 – 30°C. Protect from heat and moisture.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Bristol-Myers Squibb Canada Co., at 1-866-463-6267.