

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMYLAN-HYDROXYUREA

Hydroxyurea Capsules

Read this carefully before you start taking **MYLAN-HYDROXYUREA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MYLAN-HYDROXYUREA**.

What is MYLAN-HYDROXYUREA used for?

MYLAN-HYDROXYUREA 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.

How does MYLAN-HYDROXYUREA work?

MYLAN-HYDROXYUREA seems to interfere with the growth of cancer cells by preventing them from dividing.

What are the ingredients in MYLAN-HYDROXYUREA?

Medicinal ingredient: Hydroxyurea.

Non-medicinal ingredients: Black SW-9008/SW-9009, colloidal silicon dioxide, D&C Red #28, D&C Yellow #10, FD&C Blue #1, FD&C Red # 40, gelatin, magnesium stearate, titanium dioxide.

MYLAN-HYDROXYUREA comes in the following dosage forms:

Capsules: 500 mg hydroxyurea

Do not use MYLAN-HYDROXYUREA if:

- you have problems with your bone marrow (low blood count, severe anemia).
- you are allergic to hydroxyurea or any other component of this medication.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MYLAN-HYDROXYUREA. Talk about any health conditions or problems you may have, including if you:

- have problems with your kidneys. This is because the dose of MYLAN-HYDROXYUREA may need to be adjusted.
- have received radiation therapy. This is because your chances of developing redness of the skin are higher if MYLAN-HYDROXYUREA is used with radiation treatment.
- 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).
- recently received or are planning to receive a vaccination. Patients taking MYLAN-HYDROXYUREA should not receive live vaccines.

- 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.

Other warnings you should know about:

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

Abnormal test results: MYLAN-HYDROXYUREA can cause abnormal blood test results. Your doctor will decide when to perform blood tests. Your doctor will interpret the results.

Tumor Lysis Syndrome (TLS): MYLAN-HYDROXYUREA can cause a serious side effect known as Tumor Lysis Syndrome (TLS). It is a complication of the breakdown of cancer cells. It is serious and can lead to death. Your healthcare professional will monitor you for signs of TLS.

Hemolytic anemia: MYLAN-HYDROXYUREA may cause hemolytic anemia. Hemolytic anemia is a disorder in which the red blood cells are destroyed faster than they can be made. This will be checked by blood tests if you develop persistent anemia.

Interstitial lung disease (ILD): MYLAN-HYDROXYUREA may cause a group of disorders that inflame or scar lung tissue. 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.

Cancer: Hydroxyurea, the active ingredient in MYLAN-HYDROXYUREA, may cause cancer and damage to the genetic material in cells (DNA). Protect your skin from sun exposure and regularly examine your skin for unusual spots or moles.

Pregnancy, contraception and breastfeeding:

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 MYLAN-HYDROXYUREA. It may harm your unborn child. Use
- effective contraception methods while taking MYLAN-HYDROXYUREA and for at least 6 months afterwards.
- If you do become pregnant while taking MYLAN-HYDROXYUREA, tell your doctor right away.
- MYLAN-HYDROXYUREA can pass into your breastmilk and harm your baby. Do not breastfeed while you are taking MYLAN-HYDROXYUREA.

Male Patients:

- MYLAN-HYDROXYUREA 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 MYLAN-HYDROXYUREA.
- Avoid fathering a child during treatment. Use effective methods of birth control during your treatment with MYLAN-HYDROXYUREA and for at least one year after your last dose.

Driving and using machines: Until you know how MYLAN-HYDROXYUREA affects you, do not perform tasks which may require special attention. Do not drive, use tools or use machinery if you feel:

- drowsy,
- dizzy,
- weak or
- tired.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MYLAN-HYDROXYUREA:

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

How to take MYLAN-HYDROXYUREA:

- **ALWAYS** wear disposable gloves when handling MYLAN-HYDROXYUREA capsules and bottles containing MYLAN-HYDROXYUREA capsules.
- Take MYLAN-HYDROXYUREA exactly as your doctor has indicated.
- Swallow capsules whole.
- 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.
- If you cannot swallow MYLAN-HYDROXYUREA capsules whole, empty the contents of the capsules into a glass of water. Drink it right away. Some of the contents of the capsule may not dissolve and float on the surface.
- If any of the contents of MYLAN-HYDROXYUREA capsules are spilled, wipe it up right away with a damp disposable towel.

Usual Adult dose:

The usual dose of MYLAN-HYDROXYUREA will be different for everyone. Your healthcare professional will decide on the right dose for you. Your dose will depend on:

- what MYLAN-HYDROXYUREA is being used to treat,

- your weight, and
- if you are taking other medication.

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:

Some of the signs of an overdose could be:

- 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

If you think you, or a person you are caring for, have taken too much MYLAN-HYDROXYUREA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using MYLAN-HYDROXYUREA?

These are not all the possible side effects you may have when taking MYLAN-HYDROXYUREA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects include:

- rash, redness and ulceration in the face, skin or extremities
- skin or nail changes
- muscle aches and a general, unwell feeling or malaise
- fatigue

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Stomatitis: mouth sores, redness and swelling of the lining of the mouth	√		
Nausea: feeling the need to vomit	√		
Vomiting	√		
Diarrhea	√		
Constipation	√		
Cholestasis (decrease in bile flow from the liver): jaundice (yellowing of the skin or whites of eyes), dark urine, light coloured stools			√
Hepatitis (inflammation of the liver): Abdominal pain, fatigue, fever, itchiness,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
light coloured stool, trouble thinking clearly, yellowing of the skin and eyes			
UNCOMMON			
Loss of appetite	√		
Joint pain		√	
Drowsiness: feeling abnormally sleepy or tired during the day	√		
Headache: pain and discomfort in the head, scalp, or neck	√		
Dizziness: feeling faint, woozy, weak or unsteady	√		
Disorientation: inability to know correct time, place or person		√	
Convulsions: seizure, spasms, shaking or fits		√	
Hallucinations: seeing or hearing things that are not there		√	
Kidney problems: nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, abnormal blood test results, mental status changes (drowsiness, confusion, coma)		√	
RARE			
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			√
Dyspnea (shortness of breath)			√
Tumor lysis syndrome (the sudden, rapid death of cancer cells due to the treatment): nausea, shortness of breath, irregular heartbeat, heart rhythm disturbances, lack of urination, clouding of urine, muscle spasms or twitching, tiredness and/or joint pain, severe muscle weakness, and seizures. Metabolic disorders (kidney failure,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
abnormal heartbeat) and abnormal blood tests due to rapid breakdown of cancer cells.			
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.		√	
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	
Skin cancer (when cells in the skin become cancerous): skin nodules (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks		√	
UNKNOWN			
Interstitial lung disease (diseases that inflame or scar lung tissue): shortness of breath when rest that gets worse with exertion, dry cough			√
Hemolytic anemia (low number of red blood cells due to their faster breakdown than replacement): pale skin, feeling tired or weak, dizziness, fainting, thirst, rapid breathing		√	
Systemic lupus (an autoimmune disease that occurs when your body's immune system attacks your own tissues and organs, including your joints, skin, kidneys, blood cells, heart and lungs): fatigue, fever, joint pain, stiffness and swelling, rash on the face that covers the cheeks and the bridge of the nose or rashes elsewhere on the body, skin lesions, shortness of breath, chest pain, dry eyes, headaches, confusion and memory loss		√	
Cutaneous lupus (a form of systemic lupus that only affects the skin): scaly ring-like rash (redness with clear		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
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center), red patches on the skin, sensitivity to sunlight, rash on the face usually on cheeks and bridge of nose, ulcers in the mouth			
Fever: temporary increase in body temperature with sweating, chills, shivering, headache		√	
Chills		√	
Leukopenia (decreased white blood cells) – infections, fatigue, fever, aches, pains and flu-like symptoms		√	
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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/adverse-reaction-reporting.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.

Storage:

Store MYLAN-HYDROXYUREA at 15 – 30°C. Protect from heat and moisture. Keep out of reach and sight of children.

If you want more information about MYLAN-HYDROXYUREA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website: www.mylan.ca, or by calling 1-844-596-9526.

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