

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

MYLERAN®

busulfan tablets

Read this carefully before you start taking MYLERAN 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 MYLERAN.

Serious Warnings and Precautions

MYLERAN should only be prescribed by a healthcare professional experienced in the use of anti-cancer drugs.

Bone Marrow Suppression

Serious, irreversible bone marrow damage has been reported in people taking MYLERAN. Your healthcare professional will do blood tests at least once a week while you are taking MYLERAN. This will monitor the health of your bone marrow. If you experience any of the following symptoms while taking MYLERAN contact your healthcare professional immediately:

- symptoms of infections, including fever, chills, sore throat, mouth ulcers
- weakness, fatigue
- easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin
- rash
- shortness of breath
- pale skin, lips and nail beds

What is MYLERAN used for?

- Myleran is used in adults to manage the symptoms of Chronic granulocytic (myelocytic, myeloid) leukemia and prevent it from getting worse. Chronic granulocytic (myelocytic, myeloid) leukemia is a cancer that starts in certain blood-forming cells found in the bone marrow.
- MYLERAN can be used in patients who have not had any other treatment for their cancer.
- MYLERAN can also be used in patients who have previously had their cancer treated with radiation or P₃₂ therapy.

Use in Children

- MYLERAN should not be given to children. In children with Chronic granulocytic (myelocytic, myeloid) leukemia who were given MYLERAN before having a stem cell (bone marrow) transplant tooth problems, including white spots, pits or groves on the teeth, smaller than normal teeth and not having any adult teeth, have been seen.

How does MYLERAN work?

MYLERAN belongs to a group of anti-cancer medicines called alkylating agents. These medicines work by stopping cancer cells from growing and dividing.

What are the ingredients in MYLERAN?

Medicinal ingredients: busulfan

Non-medicinal ingredients: anhydrous lactose, hypromellose (hydroxypropyl methylcellulose), magnesium stearate, pregelatinized starch, titanium dioxide and triacetin.

MYLERAN comes in the following dosage forms:

Tablets, 2 mg

Do not use MYLERAN if:

- you are allergic (hypersensitive) to busulfan or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- you have low neutrophil (a white blood cell) or platelet cell counts.
- your cancer has shown resistance to busulfan, the medicinal ingredient in MYLERAN.

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

- have low blood counts for red blood cells, white blood cells and/or platelet cells.
- have the blood disorder thalassemia.
- have had radiation or chemotherapy in the past or are recovering from recent chemotherapy.
- are receiving or have recently received live vaccines, such as oral polio, measles, mumps and rubella.
- have had a stem cell transplant.
- have chronic lung disease.
- have had or have a history of lung or breathing problems.
- have had seizures or head trauma or taken a medicine which can cause seizures.
- have or have had a history of kidney or liver problems.
- are breastfeeding or planning to breastfeed. You should not breastfeed while taking MYLERAN. Talk to your healthcare professional about the best way to feed your baby while you are being treated with MYLERAN.
- are pregnant or planning to become pregnant. You must not get pregnant while taking MYLERAN. If you think you might be pregnant contact your healthcare professional immediately.

Other warnings you should know about:**Birth Control for Men and Women**

- Men and women must use effective birth control while taking MYLERAN.
- You must not get pregnant or father a child while taking MYLERAN. This is because MYLERAN may harm your/your female partner's unborn baby.
- Talk to your healthcare professional about the birth control methods that are right for you while you are taking MYLERAN.

Fertility in Men and Women

- MYLERAN can cause infertility in both women and men.
- This means you might not be able to get pregnant or father a child after you have finished taking MYLERAN.
- You should discuss ways to preserve your fertility with your healthcare professional before you start taking MYLERAN.
- Male patients should consider sperm preservation before they start taking MYLERAN.

Blood Tests

- Your healthcare professional will do weekly blood tests while you are taking MYLERAN.
- The blood tests will check for possible side effects and see how you are responding to MYLERAN.
- If you miss an appointment to have blood work done contact your healthcare professional immediately to reschedule.

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 MYLERAN:

- itraconazole and metronidazole, used to treat fungal infections
- other anti-cancer drugs and drugs that suppress your immune system, such as thioguanine, cyclophosphamide
- paracetamol, used to treat pain and fever
- phenytoin, used to prevent seizures
- vaccines which contain live organisms such as oral polio, measles, mumps and rubella. MYLERAN can make your body less able to fight infections.

How to take MYLERAN:

- Your healthcare professional will tell you how to take MYLERAN. Always follow their instructions.
- Do not divide the tablets. Swallow them whole with water.

Usual adult dose:

- Your healthcare professional will tell you how much MYLERAN to take and when to take it based on your height and body weight.
- Your healthcare professional may change your dose based on your blood test results and any side effects you are having.
- The maximum daily dose is 4 mg.

Overdose:

If you think you have taken too much MYLERAN, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take your dose of MYLERAN at your usual time, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a missed dose.

What are possible side effects from using MYLERAN?

These are not all the possible side effects you may feel when taking MYLERAN. If you experience any side effects not listed here, contact your healthcare professional.

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	
VERY COMMON Low levels of white blood cells (leukopenia): fever, signs of infection (sore throat, sore mouth, painful urination, blood in the urine)			√
Low levels of blood platelets (thrombocytopenia): bleeding such as nose bleeds, bleeding gums and bruising easily			√
Pneumonia syndrome: pneumonia-like symptoms (such as fever, chills, dry cough, and breathing problems)		√	
Sexual problems: - In Women: reduced fertility, missed periods early menopause (irregular or no periods, vaginal dryness, hot flashes, chills, night sweats) - In Girls: delayed or absent puberty - In Boys and Men: delayed, reduced or stopped sperm production, reduction in testicle size		√	
Nausea, vomiting, diarrhea, mouth ulcers	√		
Liver problems: yellowing of the whites of the eyes or skin (jaundice), itchiness, dark urine, pale stool, increase in waist size, weight gain, abdominal swelling and pain, loss of appetite, shortness of breath		√	

COMMON Heart problems: anxiety and restlessness, low blood pressure (lightheadedness, dizziness and fainting, especially when you go from lying or sitting to standing), weakness, chest pain, trouble breathing, dizziness or loss of consciousness		√	
Secondary leukemia (another blood cancer different from the one you are taking MYLERAN to treat): tiredness, fever or night sweats, bone/joint pain, infection and bruising/bleeding.		√	
Inflammation of the lungs: breathlessness, cough, fever		√	
Alopecia: hair loss		√	
Skin colour changes: appearance of patches of dark skin particularly on the neck, upper trunk, nipples, abdomen and creases of the hands		√	
Bladder inflammation: blood in your urine, pain when passing urine		√	
RARE Sjögren's syndrome: two most common symptoms; dry eyes and a dry mouth. Other symptoms: joint pain and swelling, swollen salivary glands, skin rash or dry skin, vaginal dryness, prolonged tiredness		√	
Aplastic anemia (severe drop in red blood cells): tiredness, weakness, bruising, infections			√
Seizure or fits		√	
Cataracts or other eye problems: cloudy or blurry vision, colours seem faded, glare from lamps or headlights, double vision		√	
Skin injury after radiation	√		

<p>Skin reactions: dry skin, rash, itchiness, lumps, blisters, fragile skin, cracked lips or corners of the mouth</p> <p>Erythema nodosum: reddish, painful, tender lumps most commonly located in the front of the legs below the knee</p>		√	
<p>Pulmonary fibrosis (scarred lung tissue): shortness of breath, especially during or after physical activity, coughing, lasting tiredness, chest discomfort, weight loss, mild fever</p>		√	
<p>VERY RARE</p> <p>Myasthenia gravis: weakness and rapid fatigue of any of the muscles under your voluntary control commonly leading to drooping eye lids and difficulty in speaking and swallowing or using your arms and legs</p>		√	
<p>Gynecomastia: enlargement of breast tissue in men</p>		√	
<p>UNKNOWN FREQUENCY</p> <p>Bone marrow suppression: infections (fever, chills, sore throat, mouth ulcers), weakness, fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin, lips and nail beds.</p>			√
<p>Glossitis: swollen and inflamed tongue, problems talking, chewing, or swallowing, especially if you get sores on your tongue</p>		√	
<p>Endocardial fibrosis (thickening of the heart muscle): breathing difficulty, grunting sounds during breathing, coughing, irregular heart beat, chest pain</p>		√	
<p>Impotence: inability to have or maintain an erection</p>	√		

Esophageal varices: blood in your vomit, black, tarry or bloody stools, lightheadedness		√	
Adrenal insufficiency: weakness, feeling very tired, weight loss, nausea, vomiting, dark skin patches		√	
Tooth hypoplasia (in children): White spots, pits, and grooves on the outer surface of the teeth; one or more teeth may appear smaller than normal, absence of permanent teeth		√	

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

MYLERAN tablets should be stored between 15° and 30°C.

Keep out of reach and sight of children.

If you want more information about MYLERAN:

- 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.html>; the manufacturer's website <http://www.aspenpharma.ca/>, or by calling 1-844-330-1213

This leaflet was prepared by Aspen Pharmacare Canada Inc.

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