READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrMYLOTARG®

gemtuzumab ozogamicin for injection

Read this carefully before you start **MYLOTARG**. 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 **MYLOTARG.**

Serious Warnings and Precautions

- Liver toxicity, including a condition called venoocclusive disease (VOD), in which the blood vessels in the liver become damaged because of blood clots
- Low number of blood cells known as neutrophils, red blood cells, white blood cells, lymphocytes, or a low number of blood cells known as platelets (with signs and symptoms such as infection, fever, bruising easily or bleeding)
- Tumor lysis syndrome (complications occurring after cancer treatment leading to increased blood levels of potassium, uric acid, and phosphorus and decreased blood levels of calcium)
- Infusion-related reactions (with signs and symptoms such as fever and chills during or shortly after the MYLOTARG infusion)

What is MYLOTARG used for?

- MYLOTARG is used to treat a certain type of cancer called acute myeloid leukaemia (AML) in which the bone marrow makes abnormal white blood cells. MYLOTARG is intended for the treatment of AML in adult patients who have not tried other treatments. MYLOTARG is not for use in patients with a type of cancer called acute promyelocytic leukaemia (APL).

How does MYLOTARG work?

MYLOTARG acts by attaching to cells with a protein called CD33. AML cells have this protein. Once attached to the AML cells, MYLOTARG delivers a substance into the cells that targets the cells' DNA and eventually kills them.

What are the ingredients in MYLOTARG?

Medicinal ingredients: gemtuzumab ozogamicin
Non-medicinal ingredients: Dextran 40; Dibasic sodium phosphate, anhydrous; Monobasic sodium phosphate, monohydrate; Sodium chloride; Sucrose

MYLOTARG comes in the following dosage forms:

MYLOTARG is supplied as a white to off-white lyophilized cake or powder in a glass vial for solution for infusion. The container is an amber Type 1 glass vial, with butyl rubber stopper and crimp seal with flip-off cap.

Do not use MYLOTARG if:

- You are allergic to gemtuzumab ozogamicin or any of the other ingredients of this medicine.

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

- have a history of liver problems or liver diseases. MYLOTARG may cause a serious life-threatening condition called hepatic venoocclusive disease (VOD), a condition in which the blood vessels in the liver become damaged and obstructed by blood clots. The signs and symptoms of VOD include, rapid weight gain, pain in the upper right side of your abdomen (belly), increase in the size of the liver, build-up of fluid causing abdominal swelling, and blood tests showing increases in bilirubin and/or liver enzymes. This condition may occur during and following treatment with MYLOTARG.
- have or think you have an infection or fever or are bruising easily or are getting frequent nose bleeds. MYLOTARG may cause a low number of blood cells known as neutrophils (sometimes accompanied with fever), red blood cells, white blood cells, lymphocytes, or a low number of blood cells known as platelets.
- have a high-pitched whistling sound during breathing (wheezing), difficulty breathing, shortness of breath, cough with or without mucous, hives, itching, swelling or have a fever and chills during or shortly after the MYLOTARG infusion.
- have symptoms in the stomach and intestines (for example, nausea, vomiting, diarrhea), heart (for example, changes in the rhythm), kidney (for example, decreased urine, blood in urine), and nerves and muscles (for example, muscular spasms, weakness, cramps), during or shortly after the MYLOTARG infusion. These may be a serious and life-threatening syndrome known as tumour lysis syndrome.

Other warnings you should know about:

Pregnancy, breast-feeding and fertility:

- If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.
- You must avoid becoming pregnant or fathering a child. Women must use 2 methods of effective contraception during treatment and for at least 7 months after the last dose of treatment. Men must use 2 methods of effective contraception during treatment and for at least 4 months after the last dose of treatment. Contact your doctor immediately if you or your partner becomes pregnant while taking this medicine.
- Seek advice regarding fertility preservation before treatment.
- If you need treatment with MYLOTARG, you must stop breast-feeding during treatment and for at least 1 month after treatment. Talk to your doctor.

Driving and using machines:

- If you feel unusually tired, dizzy or have a headache (these are very common side effects of MYLOTARG) you should not drive or use machines**.**

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

How Mylotarg is given

- Your doctor will decide on the correct dose.
- A doctor or nurse will give you MYLOTARG through a drip in your vein (intravenous infusion [IV]) gradually over 2 hours.
- Mylotarg is given in combination with chemotherapy on day 1, 4 and 7 of the first induction cycle.
- If the medicine works well, MYLOTARG can be given on day 1 of up to 2 consolidation cycles in combination with chemotherapy.
- Your doctor may change your dose, interrupt, or completely stop treatment with MYLOTARG if you have certain side effects.
- Your doctor will do blood tests during the treatment to check for side effects and for response to treatment.
- Before you receive MYLOTARG, you may be given some medicines (a corticosteroid, antihistamine, and acetaminophen) to help reduce infusion reactions symptoms such as fever and chills, which may occur during or shortly after the MYLOTARG infusion.

Usual dose:
Your doctor will decide on the correct dose.

Overdose:

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

Missed Dose:
Speak with your healthcare professional as soon as possible if you miss a dose of MYLOTARG.

What are possible side effects from using MYLOTARG?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of the side effects could be serious and may occur during or after treatment with MYLOTARG. Immediately contact your doctor if you experience any of the following serious side effects:

- Liver problems
- Bleeding
- Infections
- Complications known as tumor lysis syndrome
- Infusion reaction

Other side effects may include:

Very common (may affect more than 1 in 10 people):

- Infections (including serious infections)
- Reduced number of blood platelets (cells that help blood to clot)
- Reduced number of white blood cells which may result in general weakness and a tendency to develop infections
- Reduced number of red blood cells (anaemia) which may result in fatigue and shortness of breath
- High blood sugar

- Decreased appetite
- Headache
- Rapid heartbeat
- Bleeding
- Low blood pressure
- High blood pressure
- Shortness of breath
- Vomiting
- Diarrhoea
- Pain in the abdomen
- Feeling sick (nausea)
- Mouth inflammation
- Constipation
- Abnormalities in liver blood tests (which can be indicators of liver injury)
- Skin rash
- Fever
- Oedema (excess fluid in body tissue, causing swelling of the hands and feet)
- Fatigue
- Chills
- Changes in the levels of different enzymes in the blood (may show in your blood tests)
- Prolonged clotting time
- High level of uric acid in the blood

Common (may affect up to 1 in 10 people):
- Signs of an infusion reaction, such as a rash, shortness of breath, difficulty breathing, a tight chest, chills or fever, back pain during or after MYLOTARG infusion
- Signs of an enlarged liver (hepatomegaly), such as an enlarged belly
- Abnormal liver function
- Excessive accumulation of fluid in the abdomen/stomach
- Indigestion
- Inflammation of the oesophagus (swallowing tube)
- Liver venoocclusive disease (VOD), which includes signs of enlarged liver, pain in the upper right belly, yellowing of the skin and the whites of the eyes, accumulation of fluid in the abdomen, weight gain, abnormal liver blood tests
- Yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)
- Redness of the skin
- Itchy skin
- Organ failure

Uncommon (may affect up to 1 in 100 people):
- Liver failure
- Budd Chiari syndrome, which includes pain in the upper right part of the belly, an abnormally large liver, and/or accumulation of fluid in the belly associated with blood clots in the liver. Symptoms may also include feeling sick (nausea) and/or vomiting.

Frequency unknown (frequency cannot be estimated from the available data):
- Interstitial pneumonia (inflammation of the lungs causing coughing and difficulty breathing)
- Inflammation of the bowel in association with low white blood cell counts

- Inflammation of the urinary bladder resulting in bleeding from the bladder

These are not all the possible side effects you may feel when taking MYLOTARG. 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			
Bleeding (reduced number of platelets, cells that help blood to clot): if you bruise easily or get nose bleeds on a regular basis, or have black tarry stools, coughing up of blood, bloody sputum, or change in your mental status		√	
Infections (reduced number of white blood cells known as neutrophils): may result in general weakness and a tendency to develop infections		√	
COMMON			
Infusion reactions: such as rash, shortness of breath, difficulty breathing, a tight chest, chills or fever, back pain during or after MYLOTARG infusion		√	
Tumor lysis syndrome: if you experience dizziness, decreased urination, confusion, vomiting, nausea, swelling, shortness of breath, or heart rhythm disturbances		√	
Liver problems (**potentially life-threatening disease called venoocclusive disease):** which includes sign of enlarged liver, pain in the upper right belly, yellowing of the skin and the whites of the eyes, accumulation of in the abdomen, weight gain, abnormal liver blood tests		√	

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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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.

Reporting Suspected Side Effects

For the general public: Should you experience a side effect following treatment, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada and Pfizer Canada ULC cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following treatment, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit.

Storage:

Unopened Vial

Store in a refrigerator (2-8°C). Do not freeze.

Store in the original carton in order to protect from light.

MYLOTARG will be prepared in an infusion container by a pharmacist and then delivered to the healthcare professional who will administer the medication to you as an intravenous infusion at the hospital.

Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your doctor how to throw away medicines you no longer use. These measures will help protect the environment.

Keep out of reach and sight of children.

If you want more information about MYLOTARG

- 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; the manufacturer's website www.pfizer.ca or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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