

## Medication Information Sheet

**gemtuzumab ozogamicin** (jem-TOOZ-oo-mab oh-zoe-ga-MYE-sin)

*This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.*

**Other Name:** Mylotarg®

**Appearance:** Solution mixed into a larger bag of fluid for injection

**What is this medication for?**

- For treating a type of leukemia called acute myeloid leukemia (AML).

**What should I do before I have this medication?**

Tell your health care team if you have or had significant medical condition(s), especially if you have / had:

- liver problems or liver diseases,
- heart problems,
- bleeding problems, or
- any allergies

**Remember to:**

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

**How will this medication affect sex, pregnancy and breastfeeding?****Talk to your health care team about:**

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time until at least **7 months** after your last dose if you are female or at least **4 months** after your last dose if you are male. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication and for at least **1 month** after your last dose.

## How is this medication given?

- This drug is given through an IV (injected into a vein). Talk to your health care team about your treatment schedule.
- You will be given this treatment along with other medications to help prevent a reaction.
- If you missed your treatment appointment, talk to your health care team to find out what to do.

### To Prevent Allergic Reaction

You will be given medications before your treatment to help prevent allergic reactions before they start.

There are different types of medications to stop allergic reactions. They are called:

- antihistamines (such as diphenhydramine or Benadryl®)
- analgesics/antipyretics (such as acetaminophen or Tylenol®)
- corticosteroids (such as prednisone)

### To Prevent Tumor Lysis Syndrome (TLS)

TLS can happen when a large number of cancer cells die quickly and your body cannot get rid of them fast enough. TLS can make you very sick. Ask your health care team if you are at risk for TLS.

If you are at risk for TLS, you may be given medications before your gemtuzumab ozogamicin treatment to help prevent it.

These are called anti-uricemics (such as allopurinol), or others.

## What else do I need to know while on this medication?

- **Will this medication interact with other medications or natural health products?**
  - Although this medication is unlikely to interact with other medications, vitamins, foods and natural health products, tell your health care team about all of your:
    - prescription and over-the-counter (non-prescription) medications and all other drugs,

such as cannabis/marijuana (medical or recreational)

- natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
- ◊ Check with your health care team before starting or stopping any of them.
- **What should I do if I feel unwell, have pain, a headache or a fever?**
  - ◊ **Always** check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
    - Fever can be a sign of infection that may need treatment right away.
    - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

### How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- ◊ You have a fever if your temperature taken in your mouth (oral temperature) is:
  - 38.3°C (100.9°F) or higher at any time
- OR
- 38.0°C (100.4°F) or higher for at least one hour.

### If you do have a fever:

- ◊ **Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.**
- ◊ Ask your health care team for the [Fever](#) pamphlet for more information.

### If you do not have a fever but have mild symptoms such as headache or mild pain:

- ◊ Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)** is a safe choice for most people.
- ◊ **Talk to your health care team before you start taking** Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- ◊ Talk to your health care team if you already take **low dose aspirin** for a medical condition

(such as a heart problem). It may still be safe to take.

**What to DO while on this medication:**

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO consider asking someone to drive you to and from the hospital on your treatment days. You may feel unusually tired, drowsy or dizzy after your treatment.

**What NOT to DO while on this medication:**

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.
- DO NOT drive, operate machinery or do any tasks that need you to be alert if you feel drowsy or dizzy.

**What are the side effects of this medication?**

The following table lists side effects that you may have when getting gemtuzumab ozogamicin. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on gemtuzumab ozogamicin.

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p><b>Low platelets in the blood</b></p> <p>When platelets are low, you are at risk for bleeding and bruising. Ask your health care team for the <a href="#">Low Platelet Count</a> pamphlet for more information.</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Watch for signs of bleeding:                             <ul style="list-style-type: none"> <li>◦ bleeding from your gums</li> <li>◦ unusual or heavy nosebleeds</li> <li>◦ bruising easily or more than normal</li> <li>◦ black coloured stools (poo) or blood in your stools (poo)</li> </ul> </li> </ul>	<p>Talk to your health care team if you have any signs of bleeding. If you have bleeding that doesn't stop or is severe, you <b>MUST</b> get emergency medical help right away</p>

<b>Very Common Side Effects (50 or more out of 100 people)</b>	
<b>Side effects and what to do</b>	<b>When to contact health care team</b>
<ul style="list-style-type: none"> <li>◦ coughing up red or brown coloured mucus</li> <li>◦ dizziness, constant headache or changes in your vision</li> <li>◦ heavy vaginal bleeding</li> </ul> <p><b>What to do?</b></p> <p><b>If your health care team has told you that you have low platelets:</b></p> <ul style="list-style-type: none"> <li>• Tell your pharmacist that your platelet count may be low before taking any prescriptions or over-the-counter medication.</li> <li>• Check with your healthcare team before you go to the dentist.</li> <li>• Take care of your mouth and use a soft toothbrush.</li> <li>• Try to prevent cuts and bruises.</li> <li>• Ask your health care team what activities are safe for you.</li> <li>• Your treatment may have to be delayed if you have low platelets. Your health care team may recommend blood transfusion.</li> </ul> <p><b>If you have signs of bleeding:</b></p> <ul style="list-style-type: none"> <li>• If you have a small bleed, clean the area with soap and water or a saline (saltwater) rinse. Apply pressure for at least 10 minutes.</li> </ul> <p><b>If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.</b></p>	
<p><b>Low neutrophils (white blood cells) in the blood (neutropenia)</b></p> <p>When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the <a href="#">Neutropenia (Low white blood cell count)</a> pamphlet for more information.</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• If you feel hot or unwell (for example if you have chills or a new cough), you <b>must</b> check your temperature to see if you have a fever.</li> <li>• Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen).</li> <li>• Do not eat or drink anything hot or cold right before taking your temperature.</li> </ul> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> <li>• 38.3°C (100.9°F) or higher at any time</li> </ul> <p>OR</p>	<p>If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you <b>MUST</b> get emergency medical help right away</p>

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> <li>• 38.0°C (100.4°F) or higher for at least one hour.</li> </ul> <p><b>What to do?</b></p> <p><b>If your health care team has told you that you have low neutrophils:</b></p> <ul style="list-style-type: none"> <li>• Wash your hands often to prevent infection.</li> <li>• Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist.</li> <li>• Keep a digital thermometer at home so you can easily check for a fever.</li> </ul> <p><b>If you have a fever:</b></p> <p><b>If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.</b></p>	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p><b>Fatigue</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days.</li> <li>• Check with your health care team before starting any new exercise.</li> <li>• Pace yourself, do not rush. Put off less important activities. Rest when you need to.</li> <li>• Ask family or friends to help you with things like housework, shopping, and child or pet care.</li> <li>• Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less).</li> </ul>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> <li>• Avoid driving or using machinery if you are feeling tired.</li> </ul> <p>Ask your health care team for the <a href="#">Fatigue</a> pamphlet for more information.</p>	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p><b>Constipation</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Having bowel movements (going poo) less often than normal.</li> <li>• Small hard stools (poo) that look like pellets.</li> <li>• The need to push hard and strain to have any stool (poo) come out.</li> <li>• Stomach ache or cramps.</li> <li>• A bloated belly, feeling of fullness, or discomfort.</li> <li>• Leaking of watery stools (poo).</li> <li>• Lots of gas or burping.</li> <li>• Nausea or vomiting.</li> </ul> <p><b>What to do?</b></p> <p><b>To help prevent constipation:</b></p> <ul style="list-style-type: none"> <li>• Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains.</li> <li>• Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less.</li> <li>• Be Active. Exercise can help to keep you regular.</li> <li>• If you take opioid pain medication, ask your health care team if eating more fibre is right for you.</li> </ul> <p><b>To help treat constipation:</b></p> <ul style="list-style-type: none"> <li>• If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do.</li> </ul>	<p>Talk to your health care team if it does not improve or if it is severe</p>

<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<b>Side effects and what to do</b>	<b>When to contact health care team</b>
Ask your health care team for the <a href="#">Constipation</a> Pamphlet for more information.	
<p><b>Nausea and vomiting</b></p> <p>(Generally mild)</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Nausea is feeling like you need to throw up. You may also feel light-headed.</li> <li>• You may feel nausea within hours to days after your treatment.</li> </ul> <p><b>What to do?</b></p> <p><b>To help prevent nausea:</b></p> <ul style="list-style-type: none"> <li>• It is easier to prevent nausea than to treat it once it happens.</li> <li>• If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up.</li> <li>• Drink clear liquids and have small meals. Get fresh air and rest.</li> <li>• Do not eat spicy, fried foods or foods with a strong smell.</li> <li>• Limit caffeine (like coffee, tea) and avoid alcohol.</li> </ul> <p><b>If you have nausea or vomiting:</b></p> <ul style="list-style-type: none"> <li>• Take your rescue (as-needed) anti-nausea medication(s) as prescribed.</li> <li>• Ask your health care team for the <a href="#">Nausea &amp; Vomiting</a> pamphlet for more information.</li> <li>• Talk to your health care team if:               <ul style="list-style-type: none"> <li>◦ nausea lasts more than 48 hours</li> <li>◦ vomiting lasts more than 24 hours or if it is severe</li> </ul> </li> </ul>	<p>Contact your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours</p>



<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<b>Side effects and what to do</b>	<b>When to contact health care team</b>
<p><b>Headache</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Mild headache</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed.</li> <li>• Read the above section: <b>"What should I do if I feel unwell, have pain, a headache or a fever?"</b> before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding.</li> <li>• Rest often and try light exercise (such as walking) as it may help.</li> </ul> <p>Ask your health care team for the <a href="#">Pain</a> pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p><b>Rash; dry, itchy skin</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• You may have cracked, rough, flaking or peeling areas of the skin.</li> <li>• Your skin may look red and feel warm, like a sunburn.</li> <li>• Your skin may itch, burn, sting or feel very tender when touched.</li> </ul> <p><b>What to do?</b></p> <p><b>To prevent and treat dry skin:</b></p> <ul style="list-style-type: none"> <li>• Use fragrance-free skin moisturizer.</li> <li>• Protect your skin from the sun and the cold.</li> <li>• Use sunscreen with UVA and UVB protection and a SPF of at least 30.</li> <li>• Avoid perfumed products and lotions that contain alcohol.</li> <li>• Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less.</li> </ul> <p><b>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</b></p>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p><b>Liver problems</b></p> <p>(May be severe)</p> <p>Your health care team may check your liver function with a blood test. Liver changes do not usually cause any symptoms.</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe.</li> </ul> <p><b>What to do?</b></p> <p><b>If you have any symptoms of liver problems, get emergency medical help right away.</b></p>	<p>Get emergency medical help right away</p>

**Other rare, but serious side effects are possible.**

**If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:**

- pain in the upper right belly, yellowing of the skin and the whites of the eyes, or weight gain.
- irregular heartbeat, chest pain or fainting spells
- swelling in your hands, legs, ankles or belly
- signs of an allergic reaction such as shortness of breath, difficulty breathing or chills or fever during or after treatment
- confusion, muscle twitches and cramps or itchiness that wont go away
- pain in your lower back or changes in urination (peeing) such as less urine than usual

**Who do I contact if I have questions or need help?**

My cancer health care provider is: \_\_\_\_\_

During the day I should contact: \_\_\_\_\_

Evenings, weekends and holidays: \_\_\_\_\_

**Other Notes:**

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**June 2022** No changes made. Republished to appear on website.

*For more links on how to manage your symptoms go to [www.cancercareontario.ca/symptoms](http://www.cancercareontario.ca/symptoms).*

*The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health*

## gemtuzumab ozogamicin

*professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.*

*A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.*