

Medication Information Sheet

inotuzumab ozogamicin (IN-oh-TOOZ-ue-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: Besponsa®

Appearance: clear, colourless solution mixed into larger bags of fluids

What is this medication for?

- For treating a type of blood cancer called ALL (acute lymphoblastic leukemia) in patients who have not responded to previous treatment, or the ALL has come back after previous treatment.

What should I do before I have this medication?

- Tell your health care team if you have or had significant medical condition(s), such as:
 - ◊ liver, pancreas or gallbladder problems
 - ◊ if you have had or will have a stem cell transplant
 - ◊ heart problems, including irregular heartbeat

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

This treatment 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** while taking this drug.
 - For women: Keep using birth control for at least **8 months** after the last dose, unless your health care team told you differently.
 - For men with a partner that has a chance of becoming pregnant: Keep using birth control for at least **5 months** after the last dose, unless your health care team told you differently.
 - Talk to your health care team about which birth control options are best for you and/or your partner.
- Do not breastfeed while using this drug and for at least **2 months** after treatment ends.

How is this medication given?

- This drug is given by injection into a vein.
- Talk to your health care team about your treatment schedule.
- 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 CHOP+R 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?**
 - ◊ This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
 - ◊ Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as 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. Some vaccines cannot be given before, during, and for months after treatment with inotuzumab ozogamicin.
- DO take special care with driving, operating machinery or performing any other tasks or actions that call for alertness while on inotuzumab ozogamicin, because it may cause tiredness.

What NOT to DO 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.

What are the side effects of this medication?

The following table lists side effects that you may have when getting inotuzumab 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. Keep this paper during your treatment so that you can refer to it if you need to.

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Low neutrophils (white blood cells) in the blood (neutropenia) (May be severe)</p> <p>When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low white blood cell count) pamphlet for more information.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. • Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen). • Do not eat or drink anything hot or cold right before taking your temperature. <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> • 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. <p>What to do?</p> <p>If your health care team has told you that you have low neutrophils:</p> <ul style="list-style-type: none"> • Wash your hands often to prevent infection. • Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. • Keep a digital thermometer at home so you can easily check for a fever. <p>If you have a fever:</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 must get emergency medical help right away.</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 MUST 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
<p>Low platelets in the blood (May be severe)</p> <p>When your platelets are low, you are at risk for bleeding and bruising. Ask your health care team for the Low Platelet Count pamphlet for more information.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Watch for signs of bleeding: <ul style="list-style-type: none"> ◦ bleeding from your gums ◦ unusual or heavy nosebleeds ◦ bruising easily or more than normal ◦ black coloured stools (poo) or blood in your stools (poo) ◦ coughing up red or brown coloured mucus ◦ dizziness, constant headache or changes in your vision ◦ heavy vaginal bleeding ◦ red or pink coloured urine (pee) <p>What to do?</p> <p>If your health care team has told you that you have low platelets:</p> <ul style="list-style-type: none"> • Tell your pharmacist that your platelet count may be low before taking any prescriptions or over-the-counter medication. • Check with your healthcare team before you go to the dentist. • Take care of your mouth and use a soft toothbrush. • Try to prevent cuts and bruises. • Ask your health care team what activities are safe for you. • Your treatment may have to be delayed if you have low platelets. Your health care team may recommend a blood transfusion. <p>If you have signs of bleeding:</p> <ul style="list-style-type: none"> • 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. <p>If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.</p>	<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 (very heavy), you MUST get emergency help right away.</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Fatigue</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. <p>What to do?</p> <ul style="list-style-type: none"> • Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. • Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. • Ask family or friends to help you with things like housework, shopping, and child or pet care. • 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). • Avoid driving or using machinery if you are feeling tired. <p>Ask your health care team for the Fatigue pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Headache, Flu-like symptoms</p> <p>You may feel like you have the flu for around 2 days after your IV treatment. These flu-like symptoms may not be signs of an infection.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have chills, headache and muscle pain. • You may feel tired and have a poor appetite. • Symptoms may happen at any time after you receive your treatment and usually go away as your body gets used to the medication. <p>What to do?</p> <ul style="list-style-type: none"> • Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?" on page 3. • If you do have a fever, try to speak to your health care team. If you are unable to talk to them for advice, you MUST get emergency medical help right away. 	<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
<p>Nausea and vomiting (Generally mild)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Nausea is feeling like you need to throw up. You may also feel light-headed. • You may feel nausea within hours to days after your treatment. <p>What to do?</p> <p>To help prevent nausea:</p> <ul style="list-style-type: none"> • It is easier to prevent nausea than to treat it once it happens. • Take your anti-nausea medication(s) as prescribed, even if you do not feel like throwing up. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (like coffee, tea) and avoid alcohol. <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take your rescue (as-needed) anti-nausea medication(s) as prescribed. • Ask your health care team for the Nausea & Vomiting pamphlet for more information. • Talk to your health care team if: <ul style="list-style-type: none"> ◊ nausea lasts more than 48 hours ◊ vomiting lasts more than 24 hours or if it is severe 	<p>Talk to your health care team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if severe</p>
<p>Liver problems (May be severe)</p> <p>Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. <p>What to do?</p> <p>If you have any symptoms of liver problems, get emergency medical help right away.</p>	<p>Get emergency medical help right away</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>Pains or cramps in the belly</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Pain or cramps in your belly. • Constipation and diarrhea can cause pain in your belly. <p>What to do?</p> <ul style="list-style-type: none"> • If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Diarrhea</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. <p>What to do?</p> <p>If you have diarrhea:</p> <ul style="list-style-type: none"> • Take anti-diarrhea medication if your health care team prescribed it or told you to take it. • Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol. • Eat many small meals and snacks instead of 2 or 3 large meals. • Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. • Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. • Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. <p>Ask your health care team for the Diarrhea pamphlet for more information.</p>	<p>Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than 7 times in one day)</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>Constipation</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Having bowel movements (going poo) less often than normal. • Small hard stools (poo) that look like pellets. • The need to push hard and strain to have any stool (poo) come out. • Stomach ache or cramps. • A bloated belly, feeling of fullness, or discomfort. • Leaking of watery stools (poo). • Lots of gas or burping. • Nausea or vomiting. <p>What to do?</p> <p>To help prevent constipation:</p> <ul style="list-style-type: none"> • Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. • Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. • Be Active. Exercise can help to keep you regular. • If you take opioid pain medication, ask your health care team if eating more fibre is right for you. <p>To help treat constipation:</p> <ul style="list-style-type: none"> • 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. <p>Ask your health care team for the Constipation Pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Mouth sores</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Round, painful, white or gray sores inside your mouth that can occur on the tongue, lips, gums, or inside your cheeks. • In more severe cases they may make it hard to swallow, eat or brush your teeth. • They may last for 3 days or longer. <p>What to do?</p> <p>To help prevent mouth sores:</p> <ul style="list-style-type: none"> • Take care of your mouth by gently brushing and flossing regularly. 	<p>Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • Rinse your mouth often with a homemade mouthwash. • To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water. • Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth. <p>If you have mouth sores:</p> <ul style="list-style-type: none"> • Avoid hot, spicy, acidic, hard or crunchy foods. • Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection. • Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow. <p>Ask your health care team for the Oral Care (Mouth Care) pamphlet for more information.</p>	
<p>Low appetite</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loss of interest in food or not feeling hungry. • Weight loss. <p>What to do?</p> <ul style="list-style-type: none"> • Try to eat your favourite foods. • Eat small meals throughout the day. • You may need to take meal supplements to help keep your weight up. • Talk to your health care team if you have no appetite. <p>Ask your health care team for the Loss of Appetite pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</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:

- flushing, itchiness, rash, swollen lips, face or tongue, wheezing, chest and throat tightness, during or shortly after the drug is given
- irregular heartbeat, dizziness or fainting spells
- lower back pain, leg swelling, pee less than usual
- muscle twitching, severe weakness, cramping or feel confused

- rapid, unexpected weight gain; pain in upper right side of belly, swelling in the belly
- pain in the centre of your belly that may extend to your back

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:

inotuzumab ozogamicin

For more links on how to manage your symptoms go to 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 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.