

Medication Information Sheet

daratumumab (DAR a TOOM ue mab)

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: Darzalex®

Appearance: Clear, colourless to yellow solution, mixed into large bags of fluid

What is this medication for?

- For treating a type of blood cancer called multiple myeloma

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 (including hepatitis),
- shingles (herpes zoster), or
- or any allergies.

Daratumumab may affect certain lab tests. Be sure your health care team and the person doing your blood test know that you will be starting daratumumab. Additional blood bank lab tests are required before starting this medication.

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 until **3 months** after your last treatment dose. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this treatment.

How is this medication given?

- This medication is given through an IV (injected into a vein). Talk to your health care team about your treatment schedule.
- This medication may be given over a longer period of time for the first dose(s). If you don't have problems with the first infusion(s), it will be given over a shorter time for the following doses.
- If you missed your treatment appointment, talk to your health care team to find out what to do.
- You will be given daratumumab along with other medications to help prevent side effects or prevent a reaction.

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®)
 - H₂ blockers (such as ranitidine or famotidine)
 - corticosteroids (such as prednisone)
 - inhalers or a medication you take by mouth to keep airways open or lower irritation (if you have or had breathing problems)

To Prevent Hepatitis B Flare Ups

If you have ever been infected with hepatitis B, there is a risk that this treatment can cause it to flare up (come back). Tell your health care team if you have had hepatitis B. You may need to take medication to prevent a hepatitis B flare-up.

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.
- This drug may affect certain lab tests, such as the test for matching your blood type. This may happen for up to 6 months after your last daratumumab dose. Be sure your health care team and person doing the blood test know you are using this medication.

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 tell your health care team about any serious infections that you have now or have had in the past.

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 daratumumab. 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 daratumumab.

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Allergic reaction</p> <p>(May be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • The most common symptoms include fever, flushing, itchiness, rash, swollen lips, face or tongue, wheezing, difficulty swallowing or breathing, chest and throat tightness. • It may happen during or shortly after your treatment is given to you and may be severe. <p>What to do?</p> <ul style="list-style-type: none"> • Tell your nurse right away if you feel any signs of allergic reaction during or just after your treatment. • You may be given medicines to prevent or treat this reaction. • Talk to your health care team for advice if you have a mild skin reaction. 	<p>Get emergency medical help right away for severe symptoms.</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>Low neutrophils (white blood cells) in the blood (neutropenia)</p> <p>(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), or Advil® (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>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Low platelets in the blood</p> <p>(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>

Less Common Side Effects (10 to 24 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>Cough and feeling short of breath</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have a cough and feel short of breath. • Symptoms that commonly occur with a cough are: <ul style="list-style-type: none"> ◦ wheezing or a whistling breathing ◦ runny nose ◦ sore throat ◦ heartburn ◦ weight loss ◦ fever and chills • Rarely this may be severe with chest pain, trouble breathing or coughing up blood. <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?". 	<p>Talk to your health care team. If you are not able to talk to your health care team for advice, and you have a fever or severe symptoms, you MUST 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
<ul style="list-style-type: none"> • If you have a fever, try to talk to your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away. • If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	
<p>Mild joint, muscle pain or cramps</p> <p>What to look for?</p> <ul style="list-style-type: none"> • New pain in your muscles or joints, muscle cramps, or feeling achy. <p>What to do?</p> <ul style="list-style-type: none"> • Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. • Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" 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. • Rest often and try light exercise (such as walking) as it may help. <p>Ask your health care team for the Pain pamphlet for more information.</p>	Talk to your health care team if it does not improve or if it is severe.
<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. 	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).

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"> • 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>Nausea and vomiting</p> <p>(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. • If you were given anti-nausea medication(s), take them 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 healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours 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:

- irregular heartbeat, fainting (passing out), shortness of breath or chest pain
- yellowish skin or eyes
- pain on the right side of your belly, in the centre of your belly (may spread to your back) or pain in your lower back
- swelling in your hands, ankles, feet or other areas of your body, weight gain that is not normal for you
- unusually dark pee or peeing less 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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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.