

## Medication Information Sheet

**romidepsin** (ROE-mi-DEP 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:** Istadax®

**Appearance:** clear, colourless liquid

**What is this medication for?**

- For treating a certain type of blood cancer called Peripheral T-cell Lymphoma (PTCL)

**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:

- heart problems (including irregular or fast heartbeat),
- kidney or liver problems,
- electrolyte imbalances,
- serious infections (such as hepatitis B, cytomegalovirus (CMV) or Epstein-Barr virus), 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 **8 weeks** after your last treatment dose (if you are female) and **1 month** after your last treatment dose (if you are male).
- This medication may make hormonal birth control (such as birth control pills) that contains estrogen not work as well. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication.

## How is this medication given?

- This drug is given through an IV (injection into a vein). Talk to your health care team about your treatment schedule.
- Treatment is usually divided into cycles that are 4 weeks long. Usually you are given romidepsin on days 1, 8 and 15, followed by 13 days of rest (no treatment).
- If you missed your treatment appointment, talk to your health care team to find out what to do.

### To Prevent or Treat Nausea and Vomiting

You may be given medications to help prevent nausea (feeling like throwing up) and vomiting (throwing up) before they start.

These are called anti-nausea medications and include medications such as ondansetron (Zofran®), granisetron (Kytril®), prochlorperazine (Stemetil®) or others.

## 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 romidepsin treatment to help prevent it.

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

## 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?

- 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.
- If you are taking a blood thinner (such as warfarin), your health care team may need extra blood tests and may change your dose.

### 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.
- DO consider asking someone to drive you to and from the hospital on your treatment days. You may feel 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.

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

The following table lists side effects that you may have when getting romidepsin. 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 romidepsin.

<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>
<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>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>

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>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><b>Fatigue</b></p> <p>(May be severe)</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> <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>	<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><b>Infection</b></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 <a href="#">Neutropenia (Low white blood cell count)</a> pamphlet for more information.</p> <p>When your immune system is weakened, bacteria, viruses, or fungi that would not normally be harmful may cause an infection. If you have had hepatitis, you may get this infection again when the immune system is weakened. This happens rarely.</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> <li>• Yellowish skin or eyes, unusually dark pee or pain on the right side of your belly (hepatitis)</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 OR</li> <li>• 38.0°C (100.4°F) or higher for at least one hour.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Let your health care team know if you have had hepatitis</li> </ul> <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 health care team 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>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>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<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>	
<p><b>Low platelets in the blood</b></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 <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> <li>◦ coughing up red or brown coloured mucus</li> <li>◦ dizziness, constant headache or changes in your vision</li> <li>◦ heavy vaginal bleeding</li> <li>◦ red or pink coloured urine (pee)</li> </ul> </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 a blood transfusion.</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 (very heavy), you <b>MUST</b> 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><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>Diarrhea</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment.</li> </ul> <p><b>What to do?</b></p> <p><b>If you have diarrhea:</b></p> <ul style="list-style-type: none"> <li>Take anti-diarrhea medication if your health care team prescribed it or told you to take it.</li> <li>Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol.</li> <li>Eat many small meals and snacks instead of 2 or 3 large meals.</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>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.</li> <li>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.</li> </ul> <p>Ask your health care team for the <a href="#">Diarrhea</a> 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>

Common Side Effects (25 to 49 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>Ask your health care team for the <a href="#">Constipation</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>Liver problems</b></p> <p>(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>Get emergency medical 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><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><b>Low appetite</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Loss of interest in food or not feeling hungry.</li> <li>• Weight loss.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Try to eat your favourite foods.</li> <li>• Eat small meals throughout the day.</li> <li>• You may need to take meal supplements to help keep your weight up.</li> <li>• Talk to your health care team if you have no appetite.</li> </ul> <p>Ask your health care team for the <a href="#">Loss of Appetite</a> pamphlet for more information.</p>	Talk to your health care team if it does not improve or if it is severe

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>Taste changes</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Food and drinks may taste different than usual.</li> </ul>	Talk to your health care team if it does not improve or if it is severe

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>What to do?</b></p> <ul style="list-style-type: none"> <li>• Eat foods that are easy to chew, such as scrambled eggs, pasta, soups, cooked vegetables.</li> <li>• Taste foods at different temperatures, since the flavour may change.</li> <li>• Try different forms of foods, like fresh, frozen or canned.</li> <li>• Experiment with non-spicy foods, spices and seasonings.</li> </ul>	
<p><b>Cough and feeling short of breath</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• You may have a cough and feel short of breath.</li> <li>• Symptoms that commonly occur with a cough are: <ul style="list-style-type: none"> <li>◦ Wheezing or a whistling breathing</li> <li>◦ Runny nose</li> <li>◦ Sore throat</li> <li>◦ Heartburn</li> <li>◦ Weight loss</li> <li>◦ Fever and chills</li> </ul> </li> <li>• Rarely this may be severe with chest pain, trouble breathing or coughing up blood.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Check your temperature to see if you have a fever. Read the above section "<b>What should I do if I feel unwell, have pain, a headache or a fever?</b>".</li> <li>• If you have a fever, try to talk to your health care team. <b>If you are not able to talk to them for advice, you MUST get emergency medical help right away.</b></li> <li>• <b>If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away.</b></li> </ul>	<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 <b>MUST</b> get emergency medical help right away</p>
<p><b>Headache, mild joint, muscle pain or cramps</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Mild headache</li> <li>• New pain in your muscles or joints, muscle cramps, or feeling achy.</li> </ul>	<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>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><b>Pains or cramps in the belly</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Pain or cramps in your belly.</li> <li>• Constipation and diarrhea can cause pain in your belly.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes.</li> </ul>	Talk to your health care team if it does not improve or if it is severe
<p><b>Mouth sores</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Round, painful, white or gray sores inside your mouth that can occur on the tongue, lips, gums, or inside your cheeks.</li> <li>• In more severe cases they may make it hard to swallow, eat or brush your teeth.</li> <li>• They may last for 3 days or longer.</li> </ul> <p><b>What to do?</b></p> <p><b>To help prevent mouth sores:</b></p> <ul style="list-style-type: none"> <li>• Take care of your mouth by gently brushing and flossing regularly.</li> <li>• Rinse your mouth often with a homemade mouthwash.</li> <li>• To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water.</li> </ul>	Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow

<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>
<ul style="list-style-type: none"> <li>Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth.</li> </ul> <p><b>If you have mouth sores:</b></p> <ul style="list-style-type: none"> <li>Avoid hot, spicy, acidic, hard or crunchy foods.</li> <li>Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection.</li> <li>Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow.</li> </ul> <p>Ask your health care team for the <a href="#">Oral Care (Mouth Care)</a> pamphlet for more information.</p>	
<p><b>Too much or too little salt in your body</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>Muscle spasms, cramping, weakness, twitching, or convulsions.</li> <li>Irregular heartbeat, confusion or blood pressure changes.</li> </ul> <p><b>What to do?</b></p> <p><b>Get emergency medical help right away for severe symptoms.</b></p>	Get emergency medical help right away for severe symptoms
<p><b>Heart problems</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>You may have an irregular heartbeat, shortness of breath, chest pain or fainting spells.</li> <li>Swelling in your legs, ankles and belly.</li> <li>Sharp pain in the centre or left side of the chest (often worsens when taking a deep breath).</li> <li>Extreme tiredness that prevents you from exercising or doing normal activities.</li> </ul> <p><b>What to do?</b></p> <p><b>Get emergency medical help right away.</b></p>	Get emergency medical help right away

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>Mild swelling</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe.</li> </ul> <p><b>What to do?</b></p> <p><b>To help prevent swelling:</b></p> <ul style="list-style-type: none"> <li>Eat a low-salt diet.</li> </ul> <p><b>If you have swelling:</b></p> <ul style="list-style-type: none"> <li>Wear loose-fitting clothing.</li> <li>For swollen legs or feet, keep your feet up when sitting.</li> </ul>	<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:**

- Pain or hardening of a vein in your arm or leg,
- Confusion,
- Weight gain that is not normal for you,
- Pain in your lower back,
- Changes in urination (peeing) such as less urine than usual,
- Signs of an allergy such as rash, itchiness, swollen face, lip or tongue, chest or throat tightness

## 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: \_\_\_\_\_

