Medication Information Sheet

enasidenib (EH-nuh-SIH-deh-nib)

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: Idhifa®

Appearance: tablet in various strengths, shapes and colours

What is this medication for?

For treating a certain type of blood cancer 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:

- kidney, liver, lung 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 8 weeks after your last dose.
- This medication may make hormonal birth control (such as birth control pills) not work as well. If
 you choose to use a hormonal birth control, make sure you also use a barrier or non-hormonal
 birth control method (such as condoms). Talk to your health care team about the best birth control
 options for you.
- Do not breastfeed while on this medication and for 8 weeks after the last dose.

How is this medication given?

- This medication is usually taken once a day by mouth. Talk to your health care team about how and when to take your medication.
- Swallow whole with a glass of water, with or without food.
- If you miss a dose, take it as soon as possible if within the same day, otherwise skip it and take
 your next dose at your regularly scheduled time. Do not take an extra dose (double up) to make
 up for the missed dose.
- If you vomit (throw up) after taking your medication, talk to your health care team about what to do.
- If you take too much of your oral anticancer medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

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®), dexamethasone 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 enasidenib 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 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 medication may make hormonal birth control (such as birth control pills) not work as well. If
 you are using a hormonal birth control, talk to your health care team about the best birth control
 options for you.

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 <u>Fever</u> 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 lbuprofen (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.

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.

How should I safely store this medication?

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- How to safely touch oral anti-cancer medications

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.
- Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.
- What to do if oral anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

 Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

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

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Nausea and vomiting (Generally mild)	Talk to your health care team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if severe
 What to look for? Nausea is feeling like you need to throw up. You may also feel lightheaded. You may feel nausea within hours to days after your treatment. 	
What to do?	
 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. 	
If you have nausea or vomiting:	
 Take your rescue (as-needed) anti-nausea medication(s) as prescribed. Ask your health care team for the <u>Nausea & Vomiting</u> pamphlet for more information. Talk to your health care team if: 	
 nausea lasts more than 48 hours vomiting lasts more than 24 hours or if it is severe 	

Common Side Effects (25 to 49 out of 100 people)	
When to contact health care team	
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
Low appetite (Generally mild)	Talk to your health care team if it does not improve or if it is severe
What to look for?	
 Loss of interest in food or not feeling hungry. Weight loss. 	
What to do?	
 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. 	
Ask your health care team for the <u>Loss of Appetite</u> pamphlet for more information.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Too much or too little salt in your body What to look for? • Muscle spasms, cramping, weakness, twitching, or convulsions. • Irregular heartbeat, confusion or blood pressure changes. What to do?	Get emergency medical help right away for severe symptoms
Get emergency medical help right away for severe symptoms.	
Diarrhea What to look for? • Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment.	Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than
What to do?	7 times in one day)
If you have diarrhea:	
 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. Ask your health care team for the Diarrhea pamphlet for more information. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
What to look for? • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep.	Talk to your health care team if it does not improve or if it is severe
What to do?	
 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. 	
Ask your health care team for the <u>Fatigue</u> pamphlet for more information.	
Differentiation Syndrome	Get emergency medical help right
(May be severe) Differentiation syndrome is caused by a large, fast release of proteins (called cytokines) that help control your body's immune system and fight disease. This is a serious side effect that usually happens within 1 to 2 weeks after starting your enasidenib treatment, but it can also happen later into your treatment. If you have differentiation syndrome, it must be treated right away.	away
have differentiation syndrome, it must be treated right away. What to look for?	
 Fever, new cough, trouble breathing New swelling of arms, legs, neck, groin, or underarm area Fast weight gain, bone pain 	
What to do?	
 Your health care team may give you medications to treat the symptoms and they may monitor you in the hospital. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
If you have symptoms of differentiation syndrome, especially if they are new or severe, get emergency medical help right away.	
Taste changes	Talk to your health care team if it
(Generally mild)	does not improve or if it is severe
What to look for?	or if it is severe
Food and drinks may taste different than usual.	
What to do?	
 Eat foods that are easy to chew, such as scrambled eggs, pasta, soups, cooked vegetables. Taste foods at different temperatures, since the flavour may change. Try different forms of foods, like fresh, frozen or canned. Experiment with non-spicy foods, spices and seasonings. 	

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:

- Swelling in your hands, ankles, feet or other areas of your body
- Weight gain that is not normal for you
- Pain in your lower back
- Changes in urination (peeing) such as less urine than usual
- Muscle twitches and cramps or itchiness that won't go away
- Irregular or heartbeat, chest pain
- Confusion
- Difficulty breathing at rest, breathing that gets worse when lying down or fast breathing
- New cough, coughing up blood, shortness of breath or wheezing
- Fever (oral temperature of 38.3°C (100.9°F) or higher at any time OR 38.0°C (or 100.4°F) or higher for at least one hour)
- Unusual bruising, bleeding from your gums or nose
- Black coloured stools (poo) or blood in your stools (poo), red or pink coloured urine (pee)

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:

February 2021 New info sheet

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.