#### **Medication Information Sheet**

# azaCITIDine (tablets) (ay-za-SYE-ti-deen)

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: Onureg®

Appearance: tablet

### What is this medication for?

• For treating a type of leukemia called acute amyloid 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:

- heart problems (including abnormal heartbeat),
- kidney or liver problems, or
- any allergies

Azacitidine tablets contains a small amount of lactose. If you cannot have lactose, talk to your healthcare team.

#### 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.

You will have a blood test to check for hepatitis B before starting treatment. See the <u>Hepatitis B and Cancer Medications</u> pamphlet for more information.

## 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 6 months after your last dose.
  Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication and until at least 1 week after the last dose.

## How is this medication given?

- This medication is usually taken once a day by mouth, only on certain days of each treatment cycle. Do not take it more often or for a longer time than your doctor ordered. Talk to your health care team about how and when to take your medication.
- Take this medication with or without food at approximately the same time each day.
- Swallow tablets whole with water. Do not split, crush or chew the tablets.
- If you forget to take a dose of your medication do not take extra (double up). Take the dose as soon as possible on the same day, and take your next dose at your regular time on the next day.
- If you vomit after taking your dose, do not take another dose on that same day. Take your next dose at your regular time on the next day.
- If you take too much of your 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 will 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®) or others.

#### To Prevent or Treat Diarrhea

Diarrhea is when you have loose bowel movements (watery poo) or have bowel movements (need to go poo) more often than usual.

You may be given a medication called loperamide (Imodium®) to help prevent diarrhea before it starts or to treat diarrhea. Keep your loperamide with you all the time. When diarrhea starts, you may need to take loperamide right away. Take this medication as directed by your health care team.

If you start to have diarrhea:

- Take 2 tablets (4mg) of loperamide right away.
- Take 1 tablet (2mg) after each loose bowel movement up to a maximum of 8 tablets (16 mg) per day

### 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 timeOR
  - 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 taking azacitidine. 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 azacitidine.

Very Common Side Effects (50 or more out of 100 people	<del>)</del> )
Side effects and what to do	When to contact health care team
Nausea and vomiting (Generally mild) What to look for?	Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts
<ul> <li>Nausea is feeling like you need to throw up. You may also feel lightheaded.</li> <li>You may feel nausea within hours to days after your treatment.</li> </ul>	more than 24 hours or if it is severe.
What to do?	
To help prevent nausea:	
<ul> <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>	
If you have nausea or vomiting:	
<ul> <li>Take your rescue (as-needed) anti-nausea medication(s) as prescribed.</li> <li>Ask your health care team for the <u>Nausea &amp; Vomiting</u> pamphlet for more information.</li> <li>Talk to your health care team if:</li> </ul>	
<ul> <li>nausea lasts more than 48 hours</li> <li>vomiting lasts more than 24 hours or if it is severe</li> </ul>	

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
Diarrhea (Generally mild) What to look for?  • Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment.  What to do?	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)
If you have diarrhea:	
<ul> <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>	
Ask your health care team for the <u>Diarrhea</u> pamphlet for more information.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Low neutrophils (white blood cells) in the blood (neutropenia)  (May be severe)	If you have a fever try to contact your health care team.
When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the <a href="Neutropenia">Neutropenia</a> (Low white blood cell count) pamphlet for more information.	If you are unable to talk to the team for advice, you MUST get emergency medical help right
What to look for?	away.
<ul> <li>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.</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>	
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.	
What to do?	
If your health care team has told you that you have low neutrophils:	
<ul> <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>	
If you have a fever:	
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.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Low platelets in the blood	Talk to your health
(May be severe)	care team if you have any signs of
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">Low Platelet Count</a> pamphlet for more information.	bleeding. If you have bleeding that doesn't stop or is severe (very
What to look for?	heavy), you MUST get emergency help right away.
Watch for signs of bleeding:	neip right away.
<ul> <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>	
What to do?  If your health care team has told you that you have low platelets:	
<ul> <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>	
If you have signs of bleeding:	
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.	
If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul> <li>Constipation</li> <li>What to look for?</li> <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>	Talk to your health care team if it does not improve or if it is severe.
What to do?	
To help prevent constipation:	
<ul> <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>	
To help treat constipation:	
<ul> <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>	
Ask your health care team for the Constipation Pamphlet for more information.	
Fatigue	Talk to your health care team if it
<ul> <li>What to look for?</li> <li>Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep.</li> </ul>	does not improve or if it is severe.

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
What to do?	
<ul> <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> Ask your health care team for the <u>Fatigue</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
Mild joint, muscle pain or cramps  What to look for?  • New pain in your muscles or joints, muscle cramps, or feeling achy.	Talk to your health care team if it does not improve or if it is severe.
<ul> <li>What to do?</li> <li>Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed.</li> <li>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.</li> <li>Rest often and try light exercise (such as walking) as it may help.</li> </ul> Ask your health care team for the Pain 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
Low appetite, weight loss  What to look for?  • Loss of interest in food or not feeling hungry.  • Weight loss.	Talk to your health care team if it does not improve or if it is severe.
<ul> <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> Ask your health care team for the Loss of Appetite pamphlet for more information.	
Dizziness What to look for?  • You may feel light-headed and like you might faint (pass out).	Talk to your health care team if it does not improve or if it is severe.
<ul> <li>What to do?</li> <li>Lay down right away so you do not fall.</li> <li>Slowly get up and start moving once you feel better.</li> <li>Do not drive a motor vehicle or use machinery if you feel dizzy.</li> </ul>	

# 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 and hardening of a vein in your arms or leg
- Problems with breathing, coughing up blood
- Chest pain or irregular heartbeat
- Trouble seeing, speaking, or using your arms or legs
- Fainting spells (passing out)

## azaCITIDine (tablets)

- Yellowish skin or eyes, unusually dark pee or new pain on the right side of your belly
- Raised purple-red spots on the skin, pain and burning, itchiness
- Large, painful sores on your skin, most often on your legs
- Painful skin rash after a sudden fever that appears mostly on the arms, face and neck
- Skin that is very painful, red, warm, swollen, especially if the redness is spreading quickly, or with fever
- Fever, new cough, trouble breathing, new swelling of arms, legs, neck, groin, underarm, or bone pain
- Going pee less than usual and unexpected weight gain
- Muscle twitching with severe weakness, cramping and/or feeling confused
- Seizures

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:

azaCITIDine (tablets)

July 2023 Updated/Revised information sheet

For more links on how to manage your symptoms go to <u>www.cancercareontario.ca/symptoms</u>.

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.