

For the Patient: ULKAMLAMTN

Other Names: Maintenance Oral Azacitidine for Acute Myeloid Leukemia

- **U** = **U**ndesignated
- LK = LeuKemia
- **AML** = **A**cute **M**yeloid Leukemia
- A = Azacitidine
- MTN = MainTenaNce

ABOUT THIS TREATMENT

What are these drugs used for?

 Azacitidine (a" za sye' ti deen) is a drug that is used to treat some types of cancer, including acute myeloid leukemia (AML). It is available as oral tablets, or as a liquid that can be injected under the skin.

How do these drugs work?

 Azacitidine kills cancer cells by interfering with the genetic material of replicating cells and preventing an increase in the number of cancer cells.

INTENDED BENEFITS

- Oral azacitidine is for patients who have no more signs of acute myeloid leukemia (AML) after chemotherapy (are in remission), and who are not planned to receive a stem cell transplant.
- This therapy is being given to keep AML in remission by preventing or delaying leukemia cells from returning (relapse) and to extend life.

TREATMENT SUMMARY

How are these drugs given?

- Azacitidine tablets will be provided to you, to be taken by mouth, with or without food.
- The medication should be taken around the same time each day on treatment days.
- The medication should be swallowed whole. Do not crush or chew the tablet.
- Tablets contain lactose.
- Your treatment plan consists of chemotherapy "cycles". Each cycle lasts 4 weeks (28 days).
- Azacitidine is usually taken once daily for 14 days, followed by a 14 day break.

The calendar on the next page outlines how the medication is given for each 4 week cycle.

C V	DATE	TREATMENT PLAN		
ċ		► Week 1 → azacitidine orally once daily for 7 days		
Ē		Week 2 → azacitidine orally once daily for 7 days		
1		Week 3 no treatment		
		Week 4 🔿 no treatment		

This 28-day cycle will repeat until your treatment is completed, as determined by your cancer care team.

What will happen when I get my medication?

- A blood test is done before treatment starts.
- A blood test is also done weekly for the first cycle, then every 2 weeks for the second cycle, then before each cycle, on or before the first day of each cycle. The dose and timing of your chemotherapy may change based on your blood counts and/or other side effects.
- You will have a discussion about the chemotherapy with a member of your health care team prior to starting the medication. It is a good idea to bring someone with you to this appointment.
- You will be given a prescription for anti-nausea medications (to be filled at your regular pharmacy).
- You will need to take your anti-nausea medications at home before your chemotherapy for the first 2 cycles, until you know how the chemotherapy affects you. It is easier to prevent nausea than to treat it once it has occurred, so follow directions given to you by your cancer care team closely.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unexpected and unlikely side effects can occur with any medication treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the medication in your treatment plan.

A member of your care team will review the risks of treatment and possible side effects, and the management of side effects with you before starting treatment.

Changes in blood counts

Azacitidine may cause temporary changes in your blood counts. Your cancer care team will be following these changes carefully by performing blood tests. Adjustment of your treatment may be needed in certain circumstances.

BLOOD COUNTS	MANAGEMENT
Normal white blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.	 To help prevent infection: Wash your hands often and always after using the bathroom. Avoid crowds and people who are sick. Call your doctor <i>immediately</i> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine.
Normal platelets help your blood to clot normally after an injury (e.g., cut). When the platelet count is low, you may be more likely to bruise or bleed.	 To help prevent bleeding problems: Try not to bruise, cut, or burn yourself. Clean your nose by blowing gently. Do not pick your nose. Avoid constipation. Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding. Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). For minor pain, try acetaminophen (e.g., TYLENOL®).

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
Nausea and vomiting may occur after your treatment.	 You will be given a prescription for antinausea drug(s) to take before your chemotherapy treatment and/or at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. Drink plenty of fluids. Eat and drink often in small amounts. Try the ideas in <i>Food Choices to Help Control Nausea.</i>* Tell your healthcare team if nausea or vomiting continues or is not controlled with
	your antinausea drug(s).
Diarrhea commonly occurs. If you have	If diarrhea is a problem:
diarrhea and it is not controlled, you can	 Drink plenty of fluids.
quickly become dehydrated.	 Eat and drink often in small amounts.
	 Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea.*
	 A prescription for loperamide (IMODIUM®) is sometimes required to treat diarrhea.
	Tell your healthcare team if you have diarrhea for more than 24 hours.
	Note: If lactose in milk usually gives you diarrhea, the lactose in the tablet/capsule may be causing your diarrhea. Take LACTAID® tablets just before your azacitidine dose.
Constipation may sometimes occur.	• Exercise if you can.
	Drink plenty of fluids.
	• Try ideas in Food Choices to Manage Constipation.*

SIDE EFFECTS	MANAGEMENT
Minor bleeding, such as nosebleeds , may sometimes occur.	• Sit up straight and tip your head slightly forward. Tilting your head back may cause blood to run down your throat.
	 Pinch your nostrils shut between your thumb and forefinger or apply firm pressure against the bleeding nostril for 10 full minutes.
	 After 10 minutes, check to see if your nose is still bleeding. If it is, hold it for 10 more minutes.
	 Stay quiet for a few hours and do not blow your nose for at least 12 hours after the bleeding has stopped.
	 Get emergency help if a nosebleed lasts longer than 20 minutes
Joint pain, back pain, or pain in your arms and legs may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. Tell your healthcare team if the pain interferes with your activity.
Loss of appetite and weight loss may sometimes occur.	Try the ideas in <i>Food Ideas to Help with</i> Decreased Appetite.*
Tiredness and lack of energy may sometimes occur.	• Do not drive a car or operate machinery if you are feeling tired.
	• Try the ideas in <i>Fatigue/Tiredness</i> – <i>Patient Handout</i> .*
Hair loss does not occur with azacitidine.	

*Please ask your chemotherapy nurse or pharmacist for a copy.

STOP TAKING AZACITIDINE AND CHECK WITH YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **infection** such as fever (over 38°C or 100°F by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of **bleeding problems** such as black or tarry stools, blood in urine, pinpoint red spots on skin, or extensive bruising.
- Fainting, dizziness, or loss of consciousness.

CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

• Signs of **anemia** such as unusual tiredness or weakness.

CHECK WITH YOUR HEALTHCARE TEAM IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Easy bruising or minor bleeding.
- Pain in your stomach or excess gas.
- Feeling anxious or worried.