

Azacitidine and Venetoclax

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for acute myeloid leukemia (AML), but it may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Azacitidine (ay-zuh-SY-tih-deen): Vidaza (vih-DAY-zuh)	Attaches to DNA and RNA, stopping enzymes that add chemical tags to DNA. This helps turn on genes that stop tumors and can help cells grow or die normally.	Infusion given into a vein. OR Injection given under the skin into the stomach area (abdomen), outer upper arm, or thigh.
Venetoclax (veh-NEH-toh-klax): Venclexta (ven-KLEK-stuh)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Tablet(s) taken by mouth.

Treatment Administration and Schedule: Treatment is typically repeated every 4 weeks. This length of time is called a “cycle”.

- Azacitidine is given daily on Days 1 to 7.
- Venetoclax is taken by mouth 1 time each day.
 - Your care team will start venetoclax at a low dose. Your dose will be increased daily up to the full dose. Follow your care team’s instructions carefully while increasing to the full dose.

Treatment Name	Cycle 1, Day																												Next Cycle
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	1
Treatment Given at the Hospital or Clinic																													
Azacitidine	✓	✓	✓	✓	✓	✓	✓																						✓
Treatment Taken at Home																													
Venetoclax	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Treatment Administration and Schedule (Continued)

Your venetoclax dosing instructions:

- Venetoclax comes in 3 tablet strengths: 10 mg, 50 mg, and 100 mg.
- Take venetoclax 1 time a day with a meal and water at about the same time each day.
- Drink plenty of water during treatment with venetoclax to help reduce your risk of getting Tumor Lysis Syndrome (TLS). Drink 6 to 8 glasses (about 56 ounces total) of water each day, starting 2 days before your first dose, on the day of your first dose of venetoclax, and each time your dose is increased.
- Swallow venetoclax tablets whole. Do not chew, crush, or break the tablets.
 - Tell your care team if you have trouble swallowing 100 mg tablets. Your care team may prescribe your dose in smaller sized tablets.
- If you miss a dose of venetoclax and it has been less than 8 hours, take your dose as soon as possible. If you miss a dose of venetoclax and it has been more than 8 hours, skip the missed dose and take the next dose at your usual time.
- If you vomit after taking venetoclax, do not take an extra dose. Take the next dose at your usual time the next day.
- If you take too much venetoclax, call your care team or go to the nearest hospital emergency room right away.

Storage and Handling of Venetoclax

- Store venetoclax at or below 86°F (30°C).
- Keep venetoclax in its original container to protect from moisture.
- People who are or may become pregnant should avoid handling venetoclax. If handling is necessary, they should wear gloves.
- Keep venetoclax and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused venetoclax.

Appointments: Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	<div></div> <div></div> <div></div>	<div></div> <div></div> <div></div>
To help reduce your risk of Tumor Lysis Syndrome (TLS)	<div></div> <div></div> <div></div>	<div></div> <div></div> <div></div>
To help reduce the risk of infection	<div></div> <div></div> <div></div>	<div></div> <div></div> <div></div>
Other	<div></div> <div></div> <div></div>	<div></div> <div></div> <div></div>

Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count and Increased Risk of Infection	<p>Description: WBCs help protect the body against infections. If you have a low WBC count, you may be at a higher risk of infection.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> Wash your hands and bathe regularly. Avoid crowded places. Stay away from people who are sick. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> Fever of 100.4 °F (38°C) or higher Chills Cough Sore throat Painful urination Tiredness that is worse than normal Skin infections (red, swollen, or painful areas)
Low Platelet Count	<p>Description: Platelets help the blood clot and heal wounds. If you have low platelet counts, you are at a higher risk of bruising and bleeding.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> Blow your nose gently and avoid picking it. Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. Use an electric razor for shaving and a nail file instead of nail clippers. Avoid over-the-counter medications that may increase the risk of bleeding, such as NSAIDs. Talk with your care team or dentist before medical or dental procedures, as you may need to pause your treatment. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> Nosebleed lasting over 5 minutes despite pressure Cut that continues to bleed Significant gum bleeding when flossing or brushing Severe headaches Blood in your urine or stool Blood in your spit after a cough
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb)	<p>Description: RBCs and Hgb help bring oxygen to your body's tissues and take away carbon dioxide. If you have low RBC counts or Hgb, you may feel weak, tired, or look pale.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> Get 7 to 8 hours of sleep each night. Avoid operating heavy machinery when tired. Balance work and rest, staying active but resting when needed. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> Shortness of breath Dizziness Fast or abnormal heartbeats Severe headache

<p>Nausea and Vomiting</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. This may or may not cause vomiting.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small amounts of water, broth, or other clear liquids when you are ready to eat again. If that stays down, then try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal). Slowly work up to eating solid food. • Your care team may prescribe medicine for these symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Vomiting for more than 24 hours • Vomiting that's nonstop • Signs of dehydration (like feeling very thirsty, having a dry mouth, feeling dizzy, or having dark urine) • Blood or coffee-ground-like appearance in your vomit • Bad stomach pain that doesn't go away after vomiting
<p>Constipation</p>	<p>Description: Constipation means having a hard time passing stools or not going to the bathroom often. Your stools might feel hard and dry, which can make you uncomfortable or hurt.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how many times you move your bowels every day. • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Exercise regularly. • Eat high-fiber foods like raw fruits and vegetables. • Your care team may recommend medicine (such as polyethylene glycol 3350 or senna) for constipation. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Constipation that lasts 3 or more days • Constipation after 48 hours, even after using a laxative
<p>Diarrhea</p>	<p>Description: Diarrhea is when you have loose, watery bowel movements more often than usual. The need to use the bathroom may occur urgently.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how many times you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids every day, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid eating foods with high fiber (like raw vegetables, fruits, and whole grains), foods that cause gas (like broccoli and beans), dairy foods (like yogurt and milk), and spicy, fried, and greasy foods. • Your care team may recommend medicine (such as loperamide) for diarrhea. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Bloody diarrhea

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Tumor Lysis Syndrome (TLS)	<p>Tumor lysis happens when cancer cells break apart and flood your bloodstream with chemicals and toxins faster than your body can get rid of them. TLS is a group of conditions that affect your heart, kidneys, and muscles.</p> <p>When you first start venetoclax, you may need to take it at a hospital or clinic to be monitored for TLS.</p> <ul style="list-style-type: none"> Severe nausea, vomiting, or diarrhea Urinating smaller amounts or dark-colored urine Muscle cramps or twitching Rapid heartbeats or chest pain Confusion or weakness Seizures 	
Kidney Problems	<ul style="list-style-type: none"> Decrease in your amount of urine Blood in your urine 	<ul style="list-style-type: none"> Swelling of your ankles Loss of appetite
Liver Problems	<ul style="list-style-type: none"> Yellowing of your skin or the whites of your eyes Severe nausea or vomiting Pain on the right side of your stomach area (abdomen) 	<ul style="list-style-type: none"> Dark urine (tea colored) Bleeding or bruising more easily than normal
Injection-Site Reactions	<ul style="list-style-type: none"> Itching Swelling Bruising or bleeding 	<ul style="list-style-type: none"> Pain Rash or redness of the skin

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **harm an unborn baby**.
 - If you are able to become pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment, for 30 days after your last dose of venetoclax, and for 6 months after you last dose of azacitidine.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner(s) could become pregnant, use an effective method of birth control—such as condoms—during treatment with azacitidine and venetoclax and for 3 months after your last dose of azacitidine.
- Do NOT breastfeed** during treatment and for 1 week after your last doses of azacitidine and venetoclax.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **48 hours** after each dose of **azacitidine**:

- People who are pregnant should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don't have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

Additional Information

- **Tell your care team about all the medicines you take.**
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
 - You should not receive a “live vaccine” before, during, or after treatment with venetoclax, until your care team tells you it is okay. If you are not sure about the type of immunization or vaccine, ask your care team. These vaccines may not be safe or may not work as well during your treatment.
- **You should not drink grapefruit juice, eat grapefruit, Seville oranges (often used in marmalades), or starfruit** while you are taking venetoclax. These products may increase the amount of venetoclax in your blood.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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PES-557