VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

AML Treatment Overview

Whether you're about to begin your first acute myeloid leukemia (AML) treatment with VENCLEXTA or still deciding if it's right for you, this resource was created to help you, your family, and your caregivers navigate the journey ahead.

Inside You'll Find:

- What to Expect
- My Treatment Calendar
- Treatment Notes
- Treatment Reminders
- Glossary of Terms
- Important Safety Information

Use

VENCLEXTA is a prescription medicine used in combination with azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly diagnosed acute myeloid leukemia (AML) who:

- are 75 years of age or older, **or**
- have other medical conditions that prevent the use of standard chemotherapy.

It is not known if VENCLEXTA is safe and effective in children.

Select Important Safety Information

VENCLEXTA can cause serious side effects, including tumor lysis syndrome, low white blood cell counts, and infections. These are not all the possible side effects of VENCLEXTA. Talk to your healthcare provider for more information about the risks and side effects of VENCLEXTA.

Please see full Important Safety Information on the last page.
Please see full Prescribing Information, including Medication Guide, at https://www.rxabbvie.com/pdf/venclexta.pdf.

What to Expect

VENCLEXTA is taken in combination with azacitidine, or decitabine, or low-dose cytarabine. Your healthcare provider can advise which VENCLEXTA combination regimen may be appropriate for you.

The first few weeks of taking VENCLEXTA are crucial to the course of your treatment. While treatment for AML varies and is often unique for each person, here are some common milestones.

Week 1

- You will begin taking VENCLEXTA at a lower dose and gradually increase to your recommended dose—this is called a "**ramp-up** period"
- During this time, and potentially into week 2,* you will also be given the combination therapy that you and your healthcare provider have chosen
- Therapy in combination with VENCLEXTA will be given via IV or subcutaneous injection

*The extension into week 2 only applies to the combination therapy of VENCLEXTA + low-dose cytarabine.

Weeks 2–4

- Once you're at the full dose, continue to take VENCLEXTA as prescribed by your healthcare provider
- Lab tests will be scheduled throughout
- Work with your healthcare provider to schedule your **bone marrow biopsy**

By the End of Week 4

- A **bone marrow biopsy** should have been performed, which is necessary to establish next steps
- Once your healthcare provider performs your biopsy evaluation, they may require you to take a short treatment break or continue to the next treatment cycle

Why Bone Marrow Status Matters

A **bone marrow biopsy** by the end of week 4 will help your healthcare provider monitor your progress. The results will also help your provider determine if modifying your treatment is necessary.

My Treatment Calendar

Print out this calendar template to keep track of your dosing schedule and appointments during the first month of taking VENCLEXTA. Work with your healthcare provider to add the details of your AML treatment plan, including:

- Combination use with azacitidine, decitabine, or low-dose cytarabine treatments
- VENCLEXTA dosing
- Other medications
- Bone marrow biopsy
- Lab tests
- Transfusions

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
Add the dates & times for your azacitidine, decitabine, or cytarabine treatments						
"Ramp-up period"						
_____ *mg VENCLEXTA*	_____ *mg VENCLEXTA*	_____ *mg VENCLEXTA*	_____ *mg VENCLEXTA through day 28*			
DAY 8	**DAY 9**	**DAY 10**	**DAY 11**	**DAY 12**	**DAY 13**	**DAY 14**
DAY 15	**DAY 16**	**DAY 17**	**DAY 18**	**DAY 19**	**DAY 20**	**DAY 21**
Ask your healthcare provider about ***scheduling your bone marrow biopsy*** *by the end of your first cycle*						
DAY 22	**DAY 23**	**DAY 24**	**DAY 25**	**DAY 26**	**DAY 27**	**DAY 28**

Treatment Notes

Use this section to add any additional details about your AML treatment plan, like other medications your doctor may prescribe.

Dosing and/or duration of VENCLEXTA may vary after cycle 1 depending on your healthcare provider's guidance.

Treatment Reminders

Things to Do

- **Take VENCLEXTA** exactly as your healthcare provider tells you to take it
- **When you first take VENCLEXTA:**
  - You may need to take VENCLEXTA at a hospital or clinic to be monitored for TLS
  - Your healthcare provider will start VENCLEXTA at a low dose and slowly increase it daily up to the full dose. Follow your healthcare provider's instructions carefully while increasing to the full dose
- **Drink plenty of water** during treatment with VENCLEXTA to help reduce your risk of getting 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 VENCLEXTA, and each time your dose is increased
- **Your healthcare provider may delay, decrease your dose, or stop treatment if side effects occur**
  - When restarting VENCLEXTA after stopping for 1 week or longer, your healthcare provider may check again for risk of TLS and change your dose
- **Take VENCLEXTA 1 time a day with a meal and water** at about the same time each day
- **Swallow VENCLEXTA tablets whole**
- **Keep VENCLEXTA in original packaging** to protect from moisture
- **If you miss a dose** of VENCLEXTA and it has been less than 8 hours, take your dose as soon as possible
  - If you miss a dose of VENCLEXTA and it has been more than 8 hours, skip the missed dose and take the next dose at your usual time
- **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. VENCLEXTA and other medicines may affect each other, causing serious side effects

Things Not to Do

- **Don't change your dose of VENCLEXTA or stop taking VENCLEXTA** unless your healthcare provider tells you to
- **Don't crush, chew, or break the tablets**
- **Don't transfer tablets to a different container**
- **Don't take an extra dose if you vomit after taking VENCLEXTA.** Take the next dose at your scheduled time the next day
- **Don't drink grapefruit juice or eat grapefruit, Seville oranges (often used in marmalades), or starfruit while you are taking VENCLEXTA.** These products may increase the amount of VENCLEXTA in your blood
- **Don't start new medicines** during treatment with VENCLEXTA without first talking with your healthcare provider

VENCLEXTA can cause serious side effects, including tumor lysis syndrome (TLS).

TLS is caused by the fast breakdown of cancer cells. It can cause kidney failure, the need for dialysis treatment, and may lead to death. Your healthcare provider will do tests for TLS, so keeping appointments for those tests is important. To help reduce TLS risk, you will receive other medicines before starting and during treatment with VENCLEXTA. You may also need to receive intravenous fluids into your vein. If you have any symptoms of TLS during treatment with VENCLEXTA, including fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain, tell your healthcare provider right away.

Experiencing a medical emergency?
Dial 911 or go directly to the nearest ER.

Glossary of Terms

Here are definitions of terms that appear in this guide, as well as some others your healthcare provider may use when talking about AML. It could be helpful for you and your loved ones to use as a reference throughout your treatment journey.

Acute Myeloid Leukemia (AML) is a fast-growing cancer in which too many myeloblasts (a type of immature white blood cell) are found in the bone marrow and blood.

Bone Marrow Biopsy is a procedure in which a small sample of bone with bone marrow inside it is removed, usually from the hip bone.

Complete Remission (CR) means the blood count is normal, fewer than 5% of bone marrow cells are leukemia cells, and there are no signs or symptoms of leukemia elsewhere in the body. When there is CR:

- Patients do not need to receive red blood cell transfusions
- Patients may not need to receive platelet transfusions based on their platelet levels and if there are no signs of bleeding

Complete Remission With Partial Hematologic Recovery (CRh) means that some remission has occurred. When there is CRh, no signs of cancer are seen, but some blood counts have not returned to normal levels.

Cycle is the time it takes to complete one round of treatment. The length of one VENCLEXTA cycle is considered day 1 through day 28.

ECOG Performance Status Scale is a standardized tool used in clinical cancer trials that measures how a patient's disease impacts their day-to-day activities. Consisting of a scale of 0–5, it describes a patient's level of functioning based on their ability to care for themself, daily activity, and physical activity.

Intravenous (IV) Therapy is a way to deliver medicines, fluids, blood products, or nutrition into the bloodstream. Done by placing a flexible plastic tube (called an IV line or catheter) through the skin into a vein, it may also be referred to as infusion therapy.

Mutation or variant means any change in the DNA sequence of a cell. While changes are not inherently good or bad, some variants can lead to a disease such as cancer or increase the risk of a disease. These are referred to as pathogenic variants.

Remission means a decrease in, or disappearance of, signs and symptoms of cancer.

Subcutaneous means "beneath the skin."

Transfusion is a procedure in which whole blood or parts of blood are put into a patient's bloodstream through a vein. In the VIALE-A trial, which evaluated the safety and efficacy of VENCLEXTA in combination with azacitidine, the following definitions were used:

- Transfusion independence meant no red blood cell and no platelet transfusion during any consecutive ≥56-day post-baseline period
- Transfusion dependence meant requiring red blood cell or platelet transfusion at baseline (within 8 weeks prior to the first dose of study drug or randomization)

Use

VENCLEXTA is a prescription medicine used in combination with azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly diagnosed acute myeloid leukemia (AML) who:

- are 75 years of age or older, **or**
- have other medical conditions that prevent the use of standard chemotherapy.

It is not known if VENCLEXTA is safe and effective in children.

Important Safety Information

What is the most important information I should know about VENCLEXTA?

VENCLEXTA can cause serious side effects, including:

Tumor lysis syndrome (TLS). TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure, the need for dialysis treatment, and may lead to death. Your healthcare provider will do tests to check your risk of getting TLS before you start taking VENCLEXTA. You will receive other medicines before starting and during treatment with VENCLEXTA to help reduce your risk of TLS. You may also need to receive intravenous (IV) fluids into your vein. Your healthcare provider will do blood tests to check for TLS when you first start treatment and during treatment with VENCLEXTA. It is important to keep your appointments for blood tests. Tell your healthcare provider right away if you have any symptoms of TLS during treatment with VENCLEXTA, including fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain.

Drink plenty of water during treatment with VENCLEXTA to help reduce your risk of getting 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 VENCLEXTA, and each time your dose is increased.

Your healthcare provider may delay, decrease your dose, or stop treatment with VENCLEXTA if you have side effects. When restarting VENCLEXTA after stopping for 1 week or longer, your healthcare provider may again check for your risk of TLS and change your dose.

Who should not take VENCLEXTA?

Certain medicines must not be taken when you first start taking VENCLEXTA and while your dose is being slowly increased because of the risk of increased TLS.

- **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. VENCLEXTA and other medicines may affect each other, causing serious side effects.
- Do not start new medicines during treatment with VENCLEXTA without first talking with your healthcare provider.

Before taking VENCLEXTA, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney or liver problems.
- have problems with your body salts or electrolytes, such as potassium, phosphorus, or calcium.
- have a history of high uric acid levels in your blood or gout.
- are scheduled to receive a vaccine. You should not receive a "live vaccine" before, during, or after treatment with VENCLEXTA, until your healthcare provider tells you it is okay. If you are not sure about the type of immunization or vaccine, ask your healthcare provider. These vaccines may not be safe or may not work as well during treatment with VENCLEXTA.
- are pregnant or plan to become pregnant. VENCLEXTA may harm your unborn baby. If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with VENCLEXTA, and you should use effective birth control during treatment and for 30 days after the last dose of VENCLEXTA. If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if VENCLEXTA passes into your breast milk. Do not breastfeed during treatment with VENCLEXTA and for 1 week after the last dose.

What should I avoid while taking VENCLEXTA?

You should not drink grapefruit juice or eat grapefruit, Seville oranges (often used in marmalades), or starfruit while you are taking VENCLEXTA. These products may increase the amount of VENCLEXTA in your blood.

What are the possible side effects of VENCLEXTA?

VENCLEXTA can cause serious side effects, including:

- **Low white blood cell counts (neutropenia).** Low white blood cell counts are common with VENCLEXTA, but can also be severe. Your healthcare provider will do blood tests to check your blood counts during treatment with VENCLEXTA and may pause dosing.
- **Infections.** Death and serious infections such as pneumonia and blood infection (sepsis) have happened during treatment with VENCLEXTA. Your healthcare provider will closely monitor and treat you right away if you have a fever or any signs of infection during treatment with VENCLEXTA.

Tell your healthcare provider right away if you have a fever or any signs of an infection during treatment with VENCLEXTA.

The most common side effects of VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine in people with AML include nausea; diarrhea; low platelet count; constipation; low white blood cell count; fever with low white blood cell count; tiredness; vomiting; swelling of arms, legs, hands, or feet; fever; infection in lungs; shortness of breath; bleeding; low red blood cell count; rash; stomach (abdominal) pain; infection in your blood; muscle and joint pain; dizziness; cough; sore throat; and low blood pressure.

VENCLEXTA may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of VENCLEXTA. Call your doctor for medical advice about side effects.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you cannot afford your medication, contact genentech-access.com/patient/brands/venclexta for assistance.

Please see full Prescribing Information, including Medication Guide, at https://www.rxabbvie.com/pdf/venclexta.pdf.

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