

# Acalabrutinib, Venetoclax, and Obinutuzumab

**Care Team Contact Information:** \_\_\_\_\_

**Pharmacy Contact Information:** \_\_\_\_\_

**Diagnosis:** \_\_\_\_\_

- This treatment is often used for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- 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
Acalabrutinib (uh-KA-luh-BROO-tih-nib): Calquence (KAL-kwents)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Tablet taken by mouth.
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.
Obinutuzumab (OH-bin-yoo-TOO-zoo-mab): Gazyva (guh-ZY-vuh)	Helps your immune system find and attack cancer cells by targeting a specific protein on their surface	Infusion into a vein (intravenous (IV) infusion).

## Treatment Administration and Schedule

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

Your acalabrutinib and venetoclax dosing instructions:

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## Treatment Administration and Schedule (Continued)

### Cycle 1

- Acalabrutinib is taken 2 times a day.

### Cycle 2

- Obinutuzumab is given on Day 1 (or split across Day 1 and Day 2), then once weekly for 2 doses on Day 8 and Day 15.
- Acalabrutinib is taken 2 times a day.

Treatment Name	Cycle 2																												
	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	
<b>Treatment Given in the Clinic or Hospital</b>																													
Obinutuzumab	✓	☐						✓							✓														
<b>Treatment Taken at Home</b>																													
Acalabrutinib Morning Dose	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Acalabrutinib Evening Dose	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

### Cycles 3 to 7

- Obinutuzumab is given on Day 1.
- Acalabrutinib is taken 2 times a day.
- Venetoclax is taken 1 time a day. When you first start venetoclax, your care team will start venetoclax at a low dose. Your dose is typically increased weekly over 5 weeks up to the full dose. Follow your care team's instructions carefully while increasing to the full dose.

Treatment Name	Cycle 3																												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
<b>Treatment Given in the Clinic or Hospital</b>																													
Obinutuzumab	✓																												✓
<b>Treatment Taken at Home (Note: Venetoclax may be started in the Clinic or Hospital)</b>																													
Acalabrutinib Morning Dose	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Acalabrutinib Evening Dose	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Venetoclax	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

### Cycles 8 to 14

- Acalabrutinib is taken 2 times a day.
- Venetoclax is taken 1 time a day.

## Treatment Administration and Schedule (Continued)

### **Acalabrutinib**

- Acalabrutinib comes in 1 tablet strength: 100 mg.
- Take acalabrutinib 2 times a day, about 12 hours apart, at about the same times each day.
- Take acalabrutinib with or without food.
- Swallow acalabrutinib tablets whole with a glass of water. Do not chew, crush, dissolve, or cut tablets.
- If you miss a dose of acalabrutinib, take it as soon as you remember. If it is more than 3 hours past your usual dosing time, skip the missed dose and take your next dose of acalabrutinib at your regularly scheduled time. Do not take an extra dose to make up for a missed dose.
- If you take too much acalabrutinib, call your care team or go to the nearest hospital emergency room right away.

### **Venetoclax**

- Venetoclax comes in 3 tablet strengths: 10 mg, 50 mg, and 100 mg.
- When you first take venetoclax, you may need to take venetoclax at a hospital or clinic to be monitored for tumor lysis syndrome (TLS).
- Take venetoclax 1 time a day at about the same time each day.
- Take venetoclax with a meal and water.
- Swallow venetoclax tablets whole. Do not chew, crush, or break the 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 Acalabrutinib and Venetoclax**

- Store acalabrutinib at room temperature between 68°F and 77°F (20°C and 25°C) in a dry location.
- Store venetoclax at or below 86°F (30°C).
- Keep venetoclax in its original packaging or container to protect it from moisture.
- People who are or may become pregnant should avoid handling venetoclax without gloves.
- Keep acalabrutinib, venetoclax, and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused acalabrutinib and venetoclax.

### **Appointments**

Appointments may include regular check-ups with your care team, lab visits, treatment appointments, 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 lower the risk of infusion-related reactions	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help lower the risk of infections	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To lower the risk of Tumor Lysis Syndrome (TLS)	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<p>Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection</p>	<p>Description: WBCs help protect your body from infections. A low WBC count increases your risk of infection.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Wash your hands often and bathe regularly.</li> <li>• Avoid crowded places and close contact with people who are sick.</li> <li>• Follow food safety and wound care advice from your care team.</li> <li>• Your care team may prescribe medicine to help your WBCs recover.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Fever of 100.4°F (38°C) or higher</li> <li>• Chills</li> <li>• New or worsening cough or sore throat</li> <li>• Painful urination or signs of a urinary infection</li> <li>• Feeling much more tired than usual</li> <li>• Red, swollen, warm, or painful areas on the skin (possible skin infection)</li> </ul>
<p>Diarrhea</p>	<p>Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Keep track of how often you go to the bathroom each day.</li> <li>• Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise.</li> <li>• Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast).</li> <li>• If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods.</li> <li>• Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium).</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• 4 or more bowel movements than normal in 24 hours</li> <li>• Dizziness or lightheadedness while having diarrhea</li> <li>• Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine)</li> <li>• Bloody diarrhea</li> </ul>

Headache	<p>Description: Headaches are pain in your head that can vary in intensity, frequency, and location.</p> <p>Recommendations:</p> <ul style="list-style-type: none"><li>• Keep a headache diary to track the frequency, duration, intensity, and triggers of your headaches.</li><li>• Stay hydrated by drinking plenty of water, as dehydration can contribute to headaches.</li><li>• Apply a cold or warm compress to your forehead or neck to help ease headache pain.</li><li>• Get adequate sleep (7 to 8 hours per night) and establish a regular sleep schedule.</li><li>• Limit caffeine intake.</li><li>• Your care team may recommend medicine for headaches.</li></ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"><li>• Severe headache</li><li>• More frequent or worsening headaches</li><li>• Dizziness or feeling faint</li><li>• Confusion</li><li>• Changes in vision</li></ul>
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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
<p><b>Hepatitis B Virus (HBV) Reactivation (Boxed Warning)</b></p>	<p>Before you receive obinutuzumab, your care team will do blood tests to check for HBV infection. If you have had hepatitis B or are a carrier of hepatitis B virus, receiving obinutuzumab could cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems, including liver failure and death. Your care team will monitor you for hepatitis B infection during and for several months after you stop receiving obinutuzumab.</p> <ul style="list-style-type: none"> <li>• Worsening tiredness</li> <li>• Yellowing of your skin or white part of your eyes</li> </ul>
<p><b>Progressive Multifocal Leukoencephalopathy (PML) (Boxed Warning)</b></p>	<p>PML is a rare, serious brain infection caused by a virus that can happen in people who receive obinutuzumab. People with weakened immune systems can get PML. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML.</p> <ul style="list-style-type: none"> <li>• Confusion</li> <li>• Dizziness or loss of balance</li> <li>• Difficulty walking or talking</li> <li>• Decreased strength or weakness on one side of your body</li> <li>• Vision problems, such as blurred vision or loss of vision</li> </ul>
<p>Heart Rhythm Problems (Cardiac Arrhythmia)</p>	<ul style="list-style-type: none"> <li>• Fast or irregular heartbeat</li> <li>• Dizziness</li> <li>• Feeling faint</li> <li>• Chest discomfort</li> <li>• Shortness of breath</li> </ul>
<p>High Blood Pressure (Hypertension)</p>	<p>High blood pressure usually doesn't have symptoms but can become serious.</p> <ul style="list-style-type: none"> <li>• Severe or new headaches</li> <li>• Dizziness or lightheadedness</li> <li>• Blurred vision</li> <li>• Trouble breathing</li> <li>• Nosebleeds that do not stop</li> <li>• A pounding sensation in your chest, neck, or ears</li> <li>• Irregular or fast heartbeats</li> <li>• Chest pain or pressure</li> </ul>
<p>Low Platelet Count (Thrombocytopenia) and Increased Risk of Bleeding (Hemorrhage)</p>	<ul style="list-style-type: none"> <li>• Vomiting blood or if your vomit looks like coffee grounds</li> <li>• Pink or brown urine</li> <li>• Red or black (looks like tar) stools</li> <li>• Coughing up blood or blood clots</li> <li>• Menstrual bleeding that is heavier than normal</li> <li>• Unusual vaginal bleeding</li> <li>• Nosebleeds that happen often</li> <li>• Bruising</li> <li>• Lightheadedness</li> </ul>

<p>Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)</p>	<ul style="list-style-type: none"> <li>• Fatigue</li> <li>• Weakness</li> <li>• Pale or dull skin</li> <li>• Shortness of breath</li> <li>• Dizziness or lightheadedness</li> </ul> <ul style="list-style-type: none"> <li>• Cold hands and feet</li> <li>• Irregular heartbeat</li> <li>• Headaches</li> <li>• Chest pain</li> </ul>
<p>Tumor Lysis Syndrome (TLS)</p>	<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>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.</p> <ul style="list-style-type: none"> <li>• Severe nausea, vomiting, or diarrhea</li> <li>• Urinating smaller amounts or having dark-colored urine</li> <li>• Muscle cramps or twitching</li> <li>• Rapid heartbeats or chest pain</li> <li>• Confusion or weakness</li> <li>• Seizures</li> </ul>
<p>Infusion-Related Reactions</p>	<ul style="list-style-type: none"> <li>• Chills or shaking</li> <li>• Itching, rash, or flushing</li> <li>• Trouble breathing, wheezing, or tongue swelling</li> <li>• Dizziness or feeling faint</li> <li>• Feeling of impending doom</li> <li>• Fever of 100.4°F (38°C) or higher</li> <li>• New or severe pain in your back or neck</li> </ul>
<p>Risk of New Cancers</p>	<p>There is a risk of developing new cancers during or after treatment. Talk with your care team about this risk, and ask about the signs and symptoms of new cancers.</p>

**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 1 week after your last dose of acalabrutinib, for 30 days after your last dose of venetoclax, and for 6 months after your last dose of obinutuzumab.
    - If you think you might be pregnant or if you become pregnant, tell your care team right away.
  - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment with acalabrutinib, venetoclax, and obinutuzumab.
- **Do NOT breastfeed** during treatment, for 1 week after your last dose of venetoclax, for 2 weeks after your last dose of acalabrutinib, and for 6 months after your last dose of obinutuzumab.

## 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, 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 treatment.
- **Higher risk of bleeding after surgery.** Tell your care team if you plan to have any surgery before starting or during treatment. Your care team may ask you to stop taking acalabrutinib for 3 to 7 days before and after your surgery, depending on the type of surgery and your risk of bleeding.
- **You should not drink grapefruit juice, eat grapefruit, Seville oranges (often used in marmalades), or starfruit** during treatment with 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 care team 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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