

Chlorambucil 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
Chlorambucil (klor-AM-byoo-sil): Leukeran (LOO-keh-run)	Slows down or stops the growth of cancer cells by damaging the genetic material that cancer cells need to multiply.	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 28 days. This length of time is called a “cycle”. You will have up to 6 cycles of treatment. Your care team will advise you of the number of treatment cycles you will have.

Your chlorambucil dosing instructions:

- Chlorambucil comes in 1 tablet strength: 2 mg.
- Your dose is based on many factors, including your weight, overall health, and diagnosis.
- Take chlorambucil 1 time a day on Days 1 and 15 of each cycle, around the same time each day.
- Take chlorambucil on an empty stomach.
- Swallow chlorambucil tablets whole. Do not crush, cut, or dissolve the tablets.
- Do not change your dose or stop taking chlorambucil unless your care team tells you to.

Treatment Administration and Schedule (Continued)

- Your care team may tell you to change your dose, temporarily stop, or completely stop taking chlorambucil if you develop certain side effects.
- If you vomit or miss a dose of chlorambucil, take your next dose at your regular time. Do not take two doses at the same time.
- If you take too much chlorambucil, call your care team or go to the nearest hospital emergency room right away.

Cycle 1

- Chlorambucil is taken by mouth on Days 1 and 15
- Obinutuzumab is given on Days 1, 2, 8, and 15

Treatment Name	Cycle 1																			
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17	Day 18	...	Day 28
Treatment Taken at Home																				
Chlorambucil	✓														✓					
Treatment Given at the Clinic or Hospital																				
Obinutuzumab	✓	✓						✓							✓					

Cycles 2 to 6

- Chlorambucil is taken by mouth on Days 1 and 15
- Obinutuzumab is given on Day 1

Treatment Name	Cycle 2																				Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17	Day 18	...	Day 28	Day 1
Treatment Taken at Home																					
Chlorambucil	✓														✓						✓
Treatment Given at the Clinic or Hospital																					
Obinutuzumab	✓																				✓

Storage and Handling of Chlorambucil

- Store in the refrigerator between 36°F and 46°F (2°C and 8°C).
- If someone else is giving you your medication, they should wear gloves or pour the pills directly from the bottle into the cap, a small cup, or your hand without touching them. They should wash their hands before and after handling the pills.
- Keep chlorambucil and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused chlorambucil.

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 lower the risk of infections		
To help prevent or treat nausea and vomiting		
To help lower the risk of infusion-related reactions		
To help prevent tumor lysis syndrome (TLS)		
Other		

Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection (Boxed Warning)	Description: WBCs help protect your body from infections. A low WBC count increases your risk of infection. Recommendations: - Wash your hands often and bathe regularly. - Avoid crowded places and close contact with people who are sick. - Follow food safety and wound care advice from your care team. - Your care team may prescribe medicine to help your WBCs recover. Talk to your care team if you have: - Fever of 100.4°F (38°C) or higher - Chills - New or worsening cough or sore throat - Painful urination or signs of a urinary infection - Feeling much more tired than usual - Red, swollen, warm, or painful areas on the skin (possible skin infection)
Low Platelet Count (Thrombocytopenia) (Boxed Warning)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. Recommendations: - Blow your nose gently and avoid picking it. - Brush your teeth gently with a soft toothbrush and keep good oral hygiene. - Use an electric razor for shaving and a nail file instead of nail clippers. - Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). - Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment. Talk to your care team if you have: - A nosebleed lasting more than 5 minutes despite pressure - A cut that continues to bleed - Heavy gum bleeding when brushing or flossing - Sudden or severe headache - Blood in your urine or stool - Blood in your spit after coughing
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia) (Boxed Warning)	Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak or very tired, or may make you look pale. Recommendations: - Aim for 7 to 8 hours of sleep each night. - Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. - Balance activity and rest — stay as active as you can, but rest when needed. - Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: - Shortness of breath - Dizziness or fainting - Fast or irregular heartbeats - Sudden or severe headache

Infusion-Related Reactions	Description: An infusion reaction is a bad response that can happen during or shortly after receiving medicine through a vein. Recommendations: • Your care team may prescribe medicines before your infusion to help reduce your risk of infusion reactions or make any infusion reaction less severe. • You may be monitored for infusion reactions during each infusion. • Your care team may slow down or stop your infusion, or completely stop treatment if you have an infusion reaction. Get medical help right away if you develop any of the following during or after your infusion: • Chills or shaking • Itching, rash, or flushing • Trouble breathing, wheezing, or tongue swelling • Dizziness or feeling faint • Feeling of impending doom • Fever of 100.4°F (38°C) or higher • New or severe pain in your back or neck
Low Calcium Levels in Your Blood (Hypocalcemia)	Description: Treatment may cause low levels of calcium in your blood. Your care team will do blood tests to check you for these changes and will treat you if needed. Talk to your care team if you have: • Severe muscle cramps or spasms • Tingling or numbness around the mouth, hands, or feet • New weakness or trouble breathing • Fast, irregular, or pounding heartbeat • Confusion, fainting, or seizures • Sudden weight gain • Swelling of your arms, hands, legs, or ankles

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Hepatitis B Virus (HBV) Reactivation (Boxed Warning)	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. - Worsening tiredness - Yellowing of your skin or white part of your eyes
Progressive Multifocal Leukoencephalopathy (PML) (Boxed Warning)	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. - Confusion - Decreased strength or weakness on one side of your body - Dizziness or loss of balance - Vision problems, such as blurred vision or loss of vision - Difficulty walking or talking
Serious Infections	Fatal and serious infections have occurred in patients treated with obinutuzumab. - Fever of 100.4°F (38°C) or higher - Shortness of breath - Severe cough with or without an increase in mucus (sputum) production - Burning or pain when urinating - Severe sore throat - Unusual vaginal discharge or irritation - Redness, swelling, or pain in any part of the body
Disseminated Intravascular Coagulation (DIC)	DIC is a serious condition where clotting and bleeding happen at the same time. Small clots use up clotting factors and platelets, which can lead to uncontrolled bleeding and organ problems. - Heavy or uncontrolled bleeding (nosebleed, mouth bleeding, or bleeding from a wound) - Sudden shortness of breath, chest pain, or fast/irregular heartbeat - Many new or worsening bruises - Confusion, sudden weakness, or difficulty speaking - Blood in your urine or stool, or coughing up blood - Little or no urine output or severe abdominal pain
Seizure	- Sudden uncontrollable jerking movements - Repetitive movements (such as lip-smacking) - Loss of consciousness - Sensory disturbances (like tingling or auras) - Confusion or “staring spells” - Postictal confusion (a state of confusion after the seizure) - Muscle stiffness

Tumor Lysis Syndrome (TLS)	Tumor lysis happens when cancer cells break apart and release large amounts of substances into your bloodstream faster than your body can handle. TLS is a group of conditions that affect your heart, kidneys, and muscles. • Severe nausea, vomiting, or diarrhea • Urinating smaller amounts or having dark-colored urine • Muscle cramps or twitching • Rapid heartbeats or chest pain • Confusion or weakness • Seizures
Allergic Reactions and Serum Sickness	Serum sickness is a delayed allergic reaction that can happen days to weeks after treatment. Get emergency medical help right away if you develop any of the following signs or symptoms: • Swelling of your lips, mouth, tongue, or throat • Trouble breathing or swallowing • Raised red areas on your skin (hives) • A very fast heartbeat • You feel dizzy or faint • Chest pain or tightness • Fever of 100.4°F (38°C) or higher • Joint pain or stiffness
Risk of New Cancers	There is a risk of developing one or more new cancers during or after treatment. Talk with your care team about this risk, and ask about the signs and symptoms to watch for.

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, Fertility, 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 affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- 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 3 to 6 months after your last dose of chlorambucil, 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, for 3 to 6 months after your last dose of chlorambucil, and for 6 months after your last dose of obinutuzumab.
- **Do NOT breastfeed** during treatment with chlorambucil and for 6 months after your last dose of obinutuzumab.

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 **chlorambucil**: (Note: Obinutuzumab does not require special handling of body fluids and waste.)

- 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, 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.
- **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 to gather information and develop this patient education guide. This guide is a summary of the medication, based on information provided by the drug manufacturer and other sources.

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PES-650