Alemtuzumab

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for B-cell chronic lymphocytic leukemia (B-CLL).
- 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
Alemtuzumab (A-lem-TOO-zoo-mab): Campath (KAM-path), Lemtrada (lem-TRA-da)	Helps the immune system fight cancer by targeting and reducing certain white blood cells that can support cancer growth.	Infusion into a vein (intravenous (IV) infusion).

Note: Lemtrada is another brand name for alemtuzumab that is used to treat multiple sclerosis (MS). Lemtrada is not approved for the treatment of cancer.

Treatment Administration and Schedule

- Treatment is typically repeated 3 times a week. You may receive up to 12 weeks of treatment with alemtuzumab.
- Due to the risk of infusion-related reactions, you will receive alemtuzumab on a dose escalation schedule.
    - During the dose escalation schedule, your dose will gradually increase until you reach your full treatment dose. You will receive:
        - A smaller dose (3 mg) once a day
        - An increased dose (10 mg) once a day once you tolerate the smaller dose
        - The full treatment dose (30 mg) 3 times a week once you tolerate the increased dose
    - Dose escalation typically takes 3 to 7 days.
    - Once you reach your full treatment dose, you will receive alemtuzumab 3 times a week, with at least one day between doses.
    - If your treatment is delayed for 7 days or longer, you will need to repeat the dose escalation schedule.

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Treatment Administration and Schedule (Continued)

Dose Escalation Schedule: 3 mg

- Alemtuzumab is given every day until this dose is tolerated.

Treatment Name	Week 1	
	Day 1	…
Alemtuzumab	✓	✓

Dose Escalation Schedule: 10 mg

- Alemtuzumab is given every day until this dose is tolerated.

Treatment Name	Week 1		
	Day 1	…	Day X
Alemtuzumab			✓

Full Treatment Dose Schedule

- Alemtuzumab is given 3 times a week, with at least one day between doses.

Treatment Name	Week X							Next Week	
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 1	Day 2
Alemtuzumab		✓		✓		✓			✓

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 an appointment, call your care team as soon as possible to reschedule it.

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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		
Other	,	

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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
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: Red blood cells carry oxygen throughout your body. Low levels can make you feel tired, weak, dizzy, or short of breath. 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

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Infusion-Related Reactions (Boxed Warning)	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
Headache	Description: Headaches are pain in your head that can vary in intensity, frequency, and location. Recommendations: • Keep a headache diary to track the frequency, duration, intensity, and triggers of your headaches. • Stay hydrated by drinking plenty of water, as dehydration can contribute to headaches. • Apply a cold or warm compress to your forehead or neck to help ease headache pain. • Get adequate sleep (7 to 8 hours per night) and establish a regular sleep schedule. • Limit caffeine intake. • Your care team may recommend medicine for headaches. Talk to your care team if you have: • Severe headache • More frequent or worsening headaches • Dizziness or feeling faint • Confusion • Changes in vision

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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Stroke (Boxed Warning)	• Sudden numbness or weakness in the face, arm, or leg (especially on one side of the body) • Confusion • Trouble speaking or understanding speech • Difficulty seeing in one or both eyes • Dizziness • Loss of balance or coordination • Sudden severe headache with no known cause
Risk of New Cancers (Boxed Warning)	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.
Autoimmune Problems	Alemtuzumab may increase your risk of developing an autoimmune disease. An autoimmune disease happens when your immune system mistakenly attacks healthy cells and tissues in your body. • Unexplained weight loss or weight gain • Fast or pounding heartbeat • Feeling more tired or weak than usual • Unusual bleeding or bruising • Small red or purple spots on your skin • Blood in your urine or dark-colored urine • Swelling of your legs, ankles, or feet • Yellowing of your skin or the white part of your eyes (jaundice) • New or worsening joint pain or swelling
Thyroid Gland Problems	• Extreme tiredness • Feeling hot or cold • Your voice gets deeper • Weight gain or loss • Hair loss

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.

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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 can 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:
        - Your care team will verify your pregnancy status before treatment.
        - Use an effective method of birth control during treatment and for 3 months after your last dose of alemtuzumab.
        - 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 alemtuzumab.
- **Do not breastfeed** during treatment and for 3 months after your last dose of alemtuzumab.

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.
- **Tell your care team about all your health problems.** This includes if you have or have ever had any serious or ongoing infections. Treatment may increase your risk of certain infections or cause viruses to become active again, including cytomegalovirus (CMV) and Epstein-Barr virus (EBV). Your care team may do blood tests, monitor you during and after treatment, or give you medicines to help prevent certain infections, including pneumonia and herpes infections.
- **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

Updated Date: November 10, 2026

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