Blinatumomab

Patient Education Sheets
Understanding Your Cancer Treatment

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue 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
Blinatumomab (blih-nuh-TOO-moh-mab): Blincyto (blin-SY-toh)	Binds immune cells (T-cells) to cancer cells so T-cells can more effectively attack and destroy them.	Infusion into a vein (intravenous (IV) infusion) through an infusion pump.

Treatment Administration and Schedule

Your care team will decide the number of treatment cycles of blinatumomab.

- You will receive blinatumomab by continuous IV infusion for 4 weeks (28 days), followed by a 2-week (14 days) break during which you will not receive blinatumomab. This is 1 treatment cycle (42 days).

Treatment Name	Cycle 1								Next Cycle
	Day 1	Day 2	Day 3	…	Day 28	Day 29	…	Day 42	Day 1
Blinatumomab	→	→	→	→	→	2-week break			→

For some patients with relapsed or refractory ALL, your care team may prescribe continued therapy.

- You will receive blinatumomab by continuous IV infusion for 4 weeks (28 days), followed by an 8-week (56 days) break during which you will not receive blinatumomab. This is 1 treatment cycle (84 days).

Treatment Name	Cycle 1								Next Cycle
	Day 1	Day 2	Day 3	…	Day 28	Day 29	…	Day 84	Day 1
Blinatumomab	→	→	→	→	→	8-week break			→

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Treatment Administration and Schedule (Continued)

- Hospitalization is usually recommended when treatment begins. Depending on why you are receiving blinatumomab, you may stay in the hospital for the first 3 or 9 days of Cycle 1 and the first 2 days of Cycle 2. You may also need supervision by a healthcare professional or another hospital stay when starting a later cycle or restarting treatment after an interruption of 4 hours or longer.
- Before and during treatment with blinatumomab, you may be given chemotherapy as an injection into the space that surrounds the spinal cord and the brain (intrathecal injection) to help prevent central nervous system relapse of ALL.
- It is very important to keep the area around the IV catheter clean to reduce the risk of getting an infection. Your care team will show you how to care for your catheter site.
- Do not change the settings on your infusion pump, even if there is a problem with your pump or your pump alarm sounds. Any changes to your infusion pump settings may cause a dose that is too high or too low to be given.
- Call your care team right away if you have any problems with your pump or your pump alarm sounds.

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.

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 Cytokine Release Syndrome (CRS)		
To help prevent Tumor Lysis Syndrome (TLS)		
To help lower the risk of infections		
Other		

Common Side Effects

Side Effect	Important Information
Cytokine Release Syndrome (CRS) (Boxed Warning)	Description: CRS happens when your immune system becomes very active during treatment. It often begins within the first few days after the infusion starts. CRS can be serious, life-threatening, or fatal. Symptoms can include fever, chills, fatigue, headache, dizziness or feeling lightheaded, or difficulty breathing. Recommendations: • Keep a symptom diary to record any new or worsening symptoms such as fever, chills, fatigue, or difficulty breathing. • Your care team may ask you to monitor your temperature, blood pressure, heart rate, or oxygen level. • Stay hydrated by drinking plenty of fluids to help manage symptoms and support overall health. • If you develop CRS, do not drive or operate dangerous machinery until your care team says it is safe. • Your care team may prescribe medications for CRS. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Trouble breathing • Chills • Dizziness or light-headedness • Fast heartbeat • Headache Note: Your care team may have specific numbers for blood pressure, heart rate, and blood oxygen levels. If your numbers go beyond those limits, call your care team or get emergency help.
Neurologic Problems, Including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (Boxed Warning)	Description: Treatment can cause neurologic problems, including ICANS, that can be serious, life-threatening, or fatal. They often begin within the first 2 weeks after treatment starts but may occur at other times. You may have symptoms such as confusion, difficulty speaking, mood changes, headaches, seizures, and weakness. Recommendations: • Keep a symptom diary to track any changes in behavior, mood, or cognitive function. • Your care team will regularly check for changes in your thinking, speaking, writing, movement, and level of alertness. They may use a brief assessment called an ICE score. • Do not drive, operate heavy or potentially dangerous machinery, or perform other dangerous activities while you are receiving blinatumomab. • Monitor for neurologic symptoms such as confusion, difficulty speaking, weakness, or seizures. • Your care team may prescribe medicine for neurologic problems. Talk to your care team if you have: • Headache • Agitation, trouble staying awake, confusion or disorientation, seeing or hearing things that are not real (hallucinations) • Trouble speaking, writing, thinking, remembering things, paying attention, or understanding things • Problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms • Numbness and tingling (feeling like "pins and needles") • Burning, throbbing, or stabbing pain • Changes in your handwriting • Seizures

Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection	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) • Redness, warmth, swelling, pain, or drainage around your IV catheter
Low Platelet Count (Thrombocytopenia)	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)	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. • Your care team will monitor you for infusion reactions, especially when treatment begins or restarts. • Your care team may temporarily stop the infusion or permanently stop treatment if you have a serious 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

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
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
Liver Problems	• Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal
Inflammation of the Pancreas (Pancreatitis)	Pancreatitis may happen in people treated with blinatumomab and corticosteroids. It may be severe, life-threatening, or fatal. • Severe stomach-area pain that does not go away (with or without nausea and vomiting)

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:
        - Your care team will verify your pregnancy status before treatment.
        - Use an effective method of birth control during treatment and for 48 hours after your last dose of blinatumomab.
        - 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 blinatumomab.
- **Do not breastfeed** during treatment and for 48 hours after your last dose of blinatumomab.

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** for at least 2 weeks before starting blinatumomab, during treatment, or until your immune system has recovered after your last treatment cycle. Ask your care team before receiving any vaccine.
- **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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ACCC Association of Cancer Care Centers™
HOPA Hematology/Oncology Pharmacy Association
NCODA Network for Collaborative Oncology Development & Advancement
ONS Oncology Nursing Society

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