Glofitamab



Care Team Contact Information:	
Pharmacy Contact Information:	
Diagnosis:	
This treatment is often used for certain treatment is often used for certain treatment.	n types of lymphoma, but it may also be used for other diagnoses.
Goal of Treatment:	

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Glofitamab (gloh-FIH-tah-mab): Columvi (ko-loom-vee)	Binds immune cells (T-cells) and cancer cells together so T-cells can more effectively attack and destroy the cancer cells.	Infusion given into a vein.

Treatment Administration and Schedule: Treatment is typically repeated every 3 weeks. This length of time is called a "cycle".

Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Due to the risk of cytokine release syndrome (CRS), you will receive glofitamab on a "step-up dosing schedule".

- A single dose of a medicine called obinutuzumab will be given to you on the first day of your first treatment cycle (Day 1 of Cycle 1).
- You will start the glofitamab step-up dosing schedule a week after the obinutuzumab dose.
 - The step-up dosing schedule is when you receive smaller "step-up" doses of glofitamab on Day 8 and Day 15 of Cycle 1. This is to help reduce your risk of CRS.
 - o If your dose is delayed for any reason, you may need to repeat the "step-up dosing schedule".
- You may be hospitalized during your infusion and for 24 hours after receiving the first step-up dose on Day 8.
- You may be hospitalized during your infusion and for 24 hours after receiving the second step-up dose on Day 15 if you experienced CRS during the first step-up dose.
- You will receive your first full dose of glofitamab a week after the second step-up dose (this will be Day 1 of Cycle 2).









Treatment Administration and Schedule:

Cycle 1

	Cycle 1											
Treatment Name	Day 1	Day2	Day 3		Day 8	Day 9	Day 10		Day 15	Day 16	Day 17	 Day 21
Obinutuzumab	/											
Glofitamab					✓(Step -Up Dose 1)				✓(Step-Up Dose 2)			

Cycle 2 and Beyond

Treatment Name		Cycle 2							Next Cycle			
Name	Day 1	Day2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	 Day 21	Day1
Glofitamab	✓ (First Full Dose)											~

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







Common Side Effects

Side Effect	Important Information	
Cytokine Release Syndrome	Description: CRS happens when your immune system becomes overactive. Most CR few doses. However, some CRS events can be serious and life-threatening. Sympton lightheaded, or difficulty breathing.	
(CRS) (Boxed Warning)	 Keep a symptom diary to record any new or worsening symptoms such as fever, chills, fatigue, or difficulty breathing. Check vital signs regularly, including temperature, blood pressure, and heart rate. Stay hydrated by drinking plenty of fluids to help manage symptoms and support overall health. Your care team may prescribe medications to help manage symptoms. 	Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Trouble breathing • 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, it's important to call your care team or get emergency help.
Low White Blood Cell (WBC) Count and Increased Infection Risk	Description: WBCs help protect the body against infections. If you have a low WBC c Recommendations:	ount, you might have a higher risk of infection. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • Cough • Shortness of breath • Sore throat
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb)	Description: RBCs and Hgb help bring oxygen to your body's tissues and take away of tired, or look pale. Recommendations: Get 7 to 8 hours of sleep each night. Avoid operating heavy machinery when tired. Balance work and rest, staying active but resting when needed.	Carbon dioxide. If you have low RBC counts or Hgb, you might feel weak, Talk to your care team if you have: Shortness of breath Dizziness Fast or abnormal heartbeats Severe headache









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Low Platelet	Description: Platelets help the blood clot and heal wounds. If you have low platelet co	ounts, you might have a higher risk of bruising and bleeding.
Count	 Recommendations: Blow your nose gently and avoid picking it. Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. Use an electric razor for shaving and a nail file instead of nail clippers. Consult your care team or dentist before medical or dental procedures, as you may need to pause your medication. 	 Talk to your care team if you have: Nosebleed lasting over 5 minutes despite pressure Cut that continues to bleed Significant gum bleeding when flossing or brushing Severe headaches Blood in your urine or stool Blood in your spit after a cough
Fatigue	 Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: Routine exercise has been shown to decrease levels of fatigue. Work with your care team to find the right type of exercise for you. Ask your family and friends for help with daily tasks and emotional support. Try healthy ways to feel better, like meditation, writing in a journal, doing yoga, and using guided imagery to lower anxiety and feel good. Make a regular sleep schedule and limit naps during the day so you can sleep better at night, aiming for 7 to 8 hours of sleep. Don't use heavy machines or do things that need your full attention if you're very tired to avoid accidents. 	Talk to your care team if you have: Tiredness that affects your daily life Tiredness all the time, and it doesn't get better with rest Dizziness and weakness, along with being tired
Muscle or Joint Pain or Weakness	 Description: Muscle pain feels like soreness, aches, cramps, or stiffness in one or modappens where two bones come together and can feel sharp, dull, throbbing, or burning Recommendations: Track your pain levels, areas of discomfort, and any activities that worsen or improve your symptoms. Engage in gentle exercises like walking, stretching, or yoga to maintain mobility and strength, but consult your care team before starting any new exercise routine. Apply a warm compress to relax stiff muscles or use cold packs to reduce swelling and numb pain in affected areas. Your care team may prescribe or recommend medications, including overthe-counter pain relievers. 	









Select Rare or Serious Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Neurologic Problems This includes Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	 Headache Agitation, trouble staying awake, confusion or disorientation, seeing or hearing things that are not real (hallucinations) Trouble speaking, 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
Growth in your tumor or worsening of tumor related problems (tumor flare)	 Tender or swollen lymph nodes Pain or selling at the site of the tumor Chest pain Cough Trouble breathing

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 might get pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment and for 1 month after your last dose.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partners could be pregnant, use an effective method of birth control—such as condoms—during treatment.
- **Do NOT breastfeed** during treatment and for 1 month after your last dose.

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.
- The most common severe changes in laboratory test results are decreased white blood cells, fibrinogen, and phosphate, and increased uric acid.
- Your care team will monitor you for **signs and symptoms of CRS** during treatment with glofitamab, as well as other side effects, and treat you if needed. Your care provider may temporarily stop or completely stop your treatment with glofitamab if you develop CRS or any other side effects that are severe.
- Do not drive, operate heavy machinery, or do other dangerous activities if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of CRS or neurologic problems.
- Carry the glofitamab <u>Patient Wallet Card</u> with you at all times and show it to all of your healthcare providers.
 This card lists the signs and symptoms of CRS for which you should seek emergency medical help right away.
- This Patient Education Sheet may not describe all possible side effects.
 Call your healthcare provider 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.



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