Glofitamab-gxbm (Columvi)

About This Drug
Glofitamab-gxbm is used to treat cancer. It is given in the vein (IV).

Possible Side Effects

- Decrease in the number of white blood cells. This may raise your risk of infection.
- Increased uric acid in the blood
- Decreased fibrinogen in the blood; a protein that helps form blood clots
- Cytokine release syndrome (CRS): Some types of cancer drugs can cause CRS because of the effects of the drug in your body. If this happens you may feel very sick and get a fever, headache, nausea, or feel weak. You may also have changes to your blood pressure. Because of this, your blood pressure and pulse may be checked while you are getting this drug.
- Bone and muscle pain
- Changes in your electrolytes
- Tiredness
- Rash

Note: Each of the side effects above was reported in 20% or greater of patients treated with glofitamab-gxbm. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other drugs in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Severe cytokine release syndrome, which can be life-threatening.
- Changes in your central nervous system can happen, which can be life-threatening. The central nervous system is made up of your brain and spinal cord. You could feel headache, extreme tiredness, dizziness, tremors (shaking in parts or all of the body), confusion, disorientation, forgetfulness, trouble understanding or speaking, trouble reading or writing, numbness, tingling, weakness or pain in your hands and feet. If you start to have any of these symptoms let your doctor know right away.
- Risk of severe and life-threatening infections
• You may develop a syndrome called tumor flare reaction. Typical signs and symptoms of your cancer may worsen. You may have tender or swollen lymph nodes, pain and/or swelling at the site of your tumor, trouble breathing because of fluid build-up around your lungs.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

**Important Information**

• You will be given a Columvi Patient Wallet Card about the risk of CRS and neurologic problems that you should carry with you at all times during treatment. Show this card to any doctor or nurse who treats you.

• Due to the risk of CRS and neurologic problems, you may need to receive the first 2 doses of glofitamab-gxbm that are part of the “step-up dosing schedule” in the hospital.

• This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

• This drug may impair your ability to drive or use machinery. Use caution and talk to your doctor and/or nurse about any precautions you may need to take.

**Treating Side Effects**

• Manage tiredness by pacing your activities for the day.

• Get regular exercise, with your doctor’s approval. If you feel too tired to exercise vigorously, try taking a short walk.

• Be sure to include periods of rest between energy-draining activities.

• To decrease the risk of infection, wash your hands regularly.

• Avoid close contact with people who have a cold, the flu, or other infections.

• Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.

• To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.

• Be very careful when using knives or tools.

• Use an electric shaver instead of a razor.

• Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

• If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.

• If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

• Cytokine release syndrome may happen after your infusion. **If this happens, call 911 for emergency care.**
Food and Drug Interactions

- There are no known interactions of glofitamab-gxbm with food.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with glofitamab-gxbm. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness and/or weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Headache that does not go away
- Extreme tiredness, confusion, or forgetfulness
- Trouble understanding or speaking
- Trouble reading or writing
- Tremors
- Numbness, tingling, or pain in your hands and feet
- Wheezing and/or trouble breathing
- Pain in your chest
- Cough
- Tender or swollen lymph nodes
- Pain and/or swelling at the site of your tumor
- Signs of cytokine release syndrome such as: fever, chills, or shaking chills, feeling dizzy or lightheaded, have a headache and/or have nausea or throwing up. **If this happens, call 911 for emergency care.**
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- New rash and/or itching or a rash that is not relieved by prescribed medicines
- Pain that does not go away or is not relieved by prescribed medicine
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This drug may have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment...
and for 1 month after stopping treatment. Let your doctor know right away if you think you may be pregnant.

- **Breastfeeding warning**: Women should not breast feed during treatment and for 1 month after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.

- **Fertility warning**: Fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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