

Obinutuzumab (Gazyva)

About This Medicine

OBINUTUZUMAB (OH bi nue TOOZ ue mab) treats leukemia and lymphoma. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is a monoclonal antibody. It is given in the vein (IV).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- A decrease in the number of white blood cells. This may raise your risk of infection.
- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- While you are getting this medicine in your vein (IV), you may have a reaction to the medicine. Sometimes you may be given medicine to stop or lessen these side effects. Your care team will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. These reactions may happen after your infusion. **If this happens, call 911 for emergency care.**
- Tiredness
- Bone and muscle pain
- Cough
- Upper respiratory tract infection

Note: Each of the side effects above was reported in 20% or greater of people treated with obinutuzumab. 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 medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Severe infusion reactions and allergic reactions which can be life-threatening. Signs of allergic reaction to this medicine may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. Other symptoms of an allergic reaction can include chest pain, pain in your joints and fever. **If this happens, do not take another dose of this medicine. You should get urgent medical treatment.**



- Serum sickness- an immune reaction which can sometimes happen after your infusion. Signs may be fever, chills, rash and/or pain in the joints.
- Severe decrease in the numbers of white blood cells which can raise your risk of infection and lead to neutropenic fever, a type of fever that can develop when you have a very low number of white blood cells which can be life-threatening.
- Severe decrease in platelets which may raise your risk of bleeding, and which can be life-threatening.
- Risk of severe and life-threatening infections
- This medicine may reactivate the hepatitis B virus, which may cause liver failure and be life-threatening. Talk to your care team if you have ever had or might have a hepatitis B infection.
- A rare virus can cause an infection that affects your central nervous system, which can be life-threatening. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, have trouble understanding or speaking, trouble thinking and/or memory loss, trouble walking, eyesight changes, numbness or lack of strength to your arms, legs, or seizures. **If you start to have any of these symptoms let your care team know right away.**
- Tumor lysis syndrome: This medicine may act on the cancer cells very quickly. This may affect how your kidneys work and be life-threatening.
- A condition that causes abnormal blood clotting, which can be life-threatening. You may have abnormal bleeding and blood clots. Symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.

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

Important Information

- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment.
- Talk to your care team before receiving any vaccinations during and while you are recovering from your treatment. Some vaccinations are not recommended during or following obinutuzumab.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- 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 care team tells you, and whenever you feel like you may have a fever.
- To decrease the risk of bleeding, use a soft toothbrush. Check with your care team 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 wellbeing. Please tell your care team if you are experiencing pain.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicines that are available to help stop or lessen constipation and/or diarrhea.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Infusion reactions may occur after your infusion. **If this happens, call 911 for emergency care.**

Food and Medicine Interactions

- There are no known interactions of obinutuzumab with food.
- This medicine may interact with other medicines. Tell your care team about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call Your Care Team

Call your care team 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 or extreme weakness that interferes with your daily activities
- Extreme tiredness, agitation, or confusion
- Trouble walking
- Numbness or lack of strength to your arms and/or legs
- Trouble understanding or speaking
- Trouble thinking and/or memory loss
- Blurry vision or changes in your eyesight
- Feeling dizzy or lightheaded
- Seizures. Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors



or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**

- Wheezing and/or trouble breathing
- Cough that is bothersome, and/or coughing up yellow, green, or bloody mucus
- Your leg is swollen, red, warm and/or painful
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable.
- Pain that does not go away, or is not relieved by prescribed medicines
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, trouble urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Signs of serum sickness: fever, chills, rash, and/ or pain in the joints
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures.
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 6 months after the last dose. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 6 months after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.



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