Obinutuzumab (Gazyva)

About This Drug

Obinutuzumab is used to treat cancer. It is given in the vein (IV).

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 drug in your vein (IV), you may have a reaction to the drug. Sometimes you may be given medication to stop or lessen these side effects. Your nurse 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 patients treated with obinutuzumab given in combination with chemotherapy. Your side effects may be different depending on your specific condition. Not all possible side effects are included above.

Warnings and Precautions

- Severe infusion reactions and allergic reactions which can be life-threatening. Signs of allergic reaction to this drug 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. **If this happens, do not take another dose of this drug. You should get urgent medical treatment.**
- Severe decrease in the numbers of white blood cells and platelets which may raise your risk of infection and bleeding and which can be life-threatening.
- Risk of severe and life-threatening infections
- Reactivation of the hepatitis B virus if you have been exposed in the past, which may very rarely cause liver failure and be life-threatening.
• Changes in your central nervous system can happen which can rarely be life-threatening. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, have hallucinations (see or hear things that are not there), trouble understanding or speaking, loss of control of your bowels or bladder, eyesight changes, dizziness, loss of balance, numbness or lack of strength to your arms, legs, face, or body, seizures or coma. **If you start to have any of these symptoms let your doctor know right away.**
• Tumor lysis syndrome: This drug may act on the cancer cells very quickly. This may affect how your kidneys work and be life-threatening.

*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**

• Talk to your doctor before receiving any vaccinations during and while you are recovering from your treatment. Some vaccinations are not recommended during or following obinutuzumab.
• 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.

**Treating Side Effects**

• Manage tiredness by pacing your activities for the day.
• 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 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 wellbeing. Please tell your doctor or nurse if you are experiencing pain.
• Get regular exercise, with your doctor’s approval. If you feel too tired to exercise vigorously, try taking a short walk.
• Drink plenty of fluids (a minimum of eight glasses per day is recommended).
• 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 doctor or nurse 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 doctor or nurse before you use enemas, laxatives, or suppositories.
• Infusion reactions may occur after your infusion. **If this happens, call 911 for emergency care.**

**Food and Drug Interactions**

• There are no known interactions of obinutuzumab with food.
• Tell your doctor and pharmacist 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 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 or weakness that interferes with your daily activities
• Feeling dizzy or lightheaded
• Loss of balance
• Easy bleeding or bruising
• Confusion and/or agitation
• 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.**
• Hallucinations
• Trouble understanding or speaking
• Blurry vision or changes in your eyesight
• Numbness or lack of strength to your arms, legs, face, or body
• Wheezing and/or trouble breathing
• Coughing up yellow, green, or bloody mucus
• 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 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

• If you think you may be pregnant

**Reproduction Warnings**

• **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 6 months after treatment.

• **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should not breastfeed during treatment and for at least 6 months after 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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