

## Gemtuzumab ozogamicin (Mylotarg)

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### About This Medicine

GEMTUZUMAB OZOGAMICIN (jem TOOZ oo mab oh zoe ga MY sin) treats leukemia. 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 given in the vein (IV).

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

### Possible Side Effects

- Nausea and vomiting (throwing up)
- Constipation (not able to move bowels)
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Abnormal bleeding – 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.
- Infection
- Fever and 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.
- Changes in your liver function
- Decrease appetite (decreased hunger)
- Headache
- Rash

**Note:** Each of the side effects above was reported in greater than 15% of people treated with gemtuzumab ozogamicin. 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 changes in your liver function and blockage of small veins in the liver, which can cause liver failure and be life-threatening.
- 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 prevent or stop 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.**

- Severe abnormal bleeding which can be life-threatening
- Abnormal electrocardiogram (EKG/ECG)

**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. If you take a pill each day, follow these precautions every day.

## Treating Side Effects

- 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.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicines that are available to help stop or lessen constipation.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- 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 gemtuzumab ozogamicin 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
- Headache that does not go away
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Pain in your mouth or throat that makes it hard to eat or drink
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- No bowel movement in 3 days or when you feel uncomfortable
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, yellowing of the eyes or skin, rapid weight gain, or right upper abdomen pain and tenderness
- 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 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.**

## 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 at least 6 months after the last dose. If you can



get your partner pregnant, use birth control while taking this medicine and for at least 3 months after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.

- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for at least 1 month 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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