

Gemtuzumab ozogamicin (Mylotarg)

About This Drug

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

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 patients treated with gemtuzumab ozogamicin. Not all possible side effects are included above.

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 drug in your vein (IV), you may have a reaction to the drug. Sometimes you may be given medication to prevent or stop 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.**
- Severe abnormal bleeding which can be life-threatening
- Abnormal heartbeat/EKG

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

- 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

- 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.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- 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 nurse or doctor 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 doctor's approval, may increase your appetite.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Ask your doctor or nurse 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 doctor or nurse if you are experiencing pain.
- 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.
- 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 gemtuzumab ozogamicin with food.



- This drug may interact with other medicines. 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
- 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.
- 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
- Tiredness that interferes with your daily activities
- Headache that does not go away
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, 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 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.**
- If you think you may be pregnant or may have impregnated your partner

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. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 3 months after your cancer treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. Women should not breastfeed during treatment and for at least 1 month after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.



- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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