



Gemtuzumab Ozogamicin Injection

(jem tooz' oo mab oh'' zoe ga mye' sin)

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IMPORTANT WARNING:

Gemtuzumab ozogamicin injection should be given in a hospital or medical facility under the supervision of a doctor who is experienced in treating people who have leukemia.

Gemtuzumab ozogamicin injection should not be given with other chemotherapy medications.

Gemtuzumab ozogamicin injection causes a severe decrease in the number of all types of blood cells in your blood. This may cause certain symptoms and may increase the risk that you will develop a serious infection. If you experience any of the following symptoms, call your doctor immediately: pale skin, excessive tiredness, shortness of breath, dizziness, fast heartbeat, unusual bruising or bleeding, nosebleeds, black or tarry stool, blood in the urine, excessive vaginal bleeding, or signs of infection such as sore throat, fever, cough, and chills.

Gemtuzumab ozogamicin injection may cause serious or fatal allergic reactions which usually occur during the infusion of the medication or within 24 hours of receiving a dose. The risk that you will experience a serious allergic reaction is greater if you have lung disease or if you have a large number of white blood cells in your blood. You may be given medication or other treatment to decrease the number of white blood cells in your blood before you receive gemtuzumab ozogamicin. You also may receive certain medications before and during your infusion to prevent an allergic reaction. Your doctor will watch you carefully while you are receiving gemtuzumab ozogamicin and for at least 4 hours afterward. If you experience any of the following symptoms, tell your doctor immediately: hives; rash; itching; swelling of the eyes, face, mouth, tongue, throat, arms, hands, feet, ankles, or lower legs; hoarseness; difficulty breathing or swallowing; shortness of breath; fast, breathing; wheezing; coughing; pale or bluish skin; anxiety or restlessness; excessive sweating; fever; or chills.

Gemtuzumab ozogamicin injection may cause serious or fatal liver damage. Tell your doctor if you have had or will be having a stem cell transplant (procedure that replaces diseased bone marrow with healthy bone marrow) and if you have or have ever had liver disease. If you experience any of the following symptoms, tell your doctor immediately: fast weight gain, pain in the upper right area of the stomach, swelling of the stomach, or yellowing of the skin or eyes.

Talk to your doctor about the risks of using gemtuzumab ozogamicin injection.

Why is this medication prescribed?

Gemtuzumab ozogamicin injection is used to treat a certain type of leukemia (cancer that begins in the cells of the bone marrow) in people who are at least 60 years old, whose disease has come back after treatment with a different medication, and who cannot be treated with other medications. Gemtuzumab ozogamicin injection is in a class of medications called antineoplastic agents. It works by killing cancer cells.

How should this medicine be used?

Gemtuzumab ozogamicin comes as a powder to be mixed with water and slowly injected into a vein over 2 hours in a hospital or medical facility. It is usually given as 2 doses spaced 14 days apart.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using gemtuzumab ozogamicin injection,

- tell your doctor and pharmacist if you are allergic to gemtuzumab ozogamicin injection or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had any of the conditions mentioned in the IMPORTANT WARNING section of if you have kidney disease.
- tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant during your treatment with gemtuzumab ozogamicin. Talk to your doctor about methods of birth control that will work for you. If you become pregnant while using Gemtuzumab ozogamicin injection, call your doctor. Gemtuzumab ozogamicin injection may harm the fetus.
- do not breast-feed during your treatment with gemtuzumab ozogamicin. injection.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are being treated with gemtuzumab ozogamicin injection.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

The medical staff will give you your medication as scheduled.

What side effects can this medication cause?

Gemtuzumab ozogamicin injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- cold sores

- sores in mouth or throat
- constipation
- diarrhea
- heartburn
- loss of appetite
- headache
- back pain
- weakness
- depression
- difficulty falling asleep or staying asleep

Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- cloudy urine
- irregular heartbeat
- muscle or joint pain
- loss of muscle control
- seizures

Gemtuzumab ozogamicin injection may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

What storage conditions are needed for this medicine?

This medication will be stored in the hospital or medical facility where you receive each dose.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to gemtuzumab ozogamicin injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Mylotarg®

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