



Alemtuzumab Injection

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IMPORTANT WARNING:

Alemtuzumab injection may cause a decrease in the number of blood cells made by your bone marrow. If you experience any of the following symptoms, call your doctor immediately: unusual bruising or bleeding, small reddish or purple blood spots on your body, pale skin, weakness, or excessive tiredness. You will need to take extra precautions to avoid injury during your treatment because you may bleed heavily from minor cuts or scrapes. Brush your teeth with a soft toothbrush, use an electric razor if you shave, and avoid contact sports and other activities that may cause injury.

Alemtuzumab injection may decrease your ability to fight infection and increase the risk that you will get a serious or life threatening infection. Call your doctor immediately if you develop any signs of infection such as fever (temperature > 100.4^o F), cough, sore throat, or a wound that is red, oozing pus, or slow to heal.

You will need to take precautions to decrease the risk of infection during your treatment with alemtuzumab injection. Your doctor will prescribe certain medications to prevent infection. You will take these medications during your treatment and for at least 2 months after your treatment. Take these medications exactly as directed. You should also wash your hands often and avoid people who have contagious infections such as coughs and colds. If you need any type of blood transfusion during your treatment with alemtuzumab injection, you should receive only irradiated blood products (blood products that have been treated to prevent a certain serious reaction that may occur in people who have weakened immune systems).

Talk to your doctor before receiving any vaccines during your treatment with alemtuzumab injection or after your treatment has been completed. Also ask your doctor if you and your family should receive the flu vaccine.

You may experience a serious or fatal reaction while you receive a dose of alemtuzumab injection. You will receive each dose of medication in a medical facility, and your doctor will monitor you carefully while you are receiving the medication. Your doctor will prescribe certain medications to prevent these reactions. You will take these medications by mouth shortly before you receive each dose of alemtuzumab. Your doctor will start you on a low dose of alemtuzumab and gradually increase your dose to allow your body to adjust to the medication. If you experience any of the following symptoms during or after your infusion, tell your doctor immediately: fever; chills; nausea; vomiting; hives; rash; itching; difficulty breathing or swallowing; slowed breathing; tightening of the throat; swelling of the eyes, face, mouth, lips, tongue or throat; hoarseness; dizziness; lightheadedness; fainting; fast or irregular

heartbeat; or chest pain.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests during and after your treatment to check your body's response to alemtuzumab injection.

Talk to your doctor about the risks of receiving alemtuzumab injection.

Why is this medication prescribed?

Alemtuzumab injection is used to treat B-chronic lymphocytic leukemia (a slowly developing cancer in which too many of a certain type of white blood cell accumulate in the body). Alemtuzumab is in a class of medications called monoclonal antibodies. It works by activating the immune system to destroy cancer cells.

How should this medicine be used?

Alemtuzumab injection comes as a solution (liquid) to be injected intravenously (into a vein) over at least 2 hours by a doctor or nurse in a hospital or medical office. At first, alemtuzumab injection is usually given in gradually increasing doses for 3 to 7 days to allow the body to adjust to the medication. Once the body has adjusted to the needed dose of alemtuzumab injection, the medication is usually given three times weekly on alternate days (usually Monday, Wednesday, and Friday) for up to 12 weeks.

The medications you receive before each dose of alemtuzumab injection might make you sleepy. You will probably want to ask a family member or friend to come with you when you receive your medication and to take you home afterward.

Although your condition may improve as soon as 4 to 6 weeks after you begin treatment with alemtuzumab injection, your treatment will probably last for 12 weeks. Your doctor will decide whether to continue your treatment and may adjust your dose depending on how well the medication works for you and on the side effects you experience.

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 receiving alemtuzumab injection,

- tell your doctor and pharmacist if you are allergic to alemtuzumab 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.
- tell your doctor if you have or have ever had any medical conditions.
- tell your doctor if you or your partner are pregnant or plan to become pregnant. You or your partner should not become pregnant during your treatment with alemtuzumab injection or for 6 months after your treatment. Talk to your doctor about types of birth control that you can use to prevent pregnancy during this time. If you or your partner becomes pregnant while you are receiving alemtuzumab injection, call your doctor.
- tell your doctor if you are breast-feeding. Your doctor may tell you not to breast-feed during your treatment and for several months after your treatment.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are receiving alemtuzumab injection.

What special dietary instructions should I follow?

Talk to your doctor about what you should eat during your treatment. It is important to eat a balanced diet that includes protein and to drink 8 to 10 glasses of water every day. Avoid the following foods that may cause infection: peel or skin of fresh fruits or vegetables; unpasteurized juices or dairy products; certain cheeses; meat or poultry that has been allowed to defrost at room temperature on a counter; and meat, poultry, fish, or eggs that have not been cooked thoroughly.

If you develop anemia (low red blood cell count) during your treatment, your doctor may recommend that you eat foods that are rich in iron such as meats, leafy green vegetables, and fortified grains and cereals. You will get the most iron from these foods if you eat them along with foods that contain vitamin C or vitamin C supplements. Your doctor may also prescribe an iron supplement for you to take during your treatment.

What side effects can this medication cause?

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

- nausea
- vomiting
- stomach pain
- diarrhea
- loss of appetite
- mouth sores
- headache
- anxiety
- difficulty falling asleep or staying asleep
- uncontrollable shaking of a part of the body
- muscle pain

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

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

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

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.

Symptoms of overdose may include:

- tightening of the throat
- difficulty breathing
- cough
- decreased urination
- unusual bruising or bleeding
- reddish or purple spots on the skin

- pale skin
- weakness
- excessive tiredness
- sore throat, fever, chills, and other signs of infection
- nausea
- vomiting
- hives
- rash
- itching
- swelling of the eyes, face, mouth, throat, lips, or tongue
- fast or irregular heartbeat
- fainting
- chest pain

What other information should I know?

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

- Campath®

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