

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}MabCampath® (pronounced 'mabCAMpath')

(Alemtuzumab)

Read this carefully before you start taking **MabCampath** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MabCampath**.

Serious Warnings and Precautions

MabCampath should be administered under the supervision of a physician experienced in the use of cancer therapy.

- **Blood disorders:** Serious, and in rare instances fatal, blood disorders have occurred in patients receiving MabCampath therapy (see [Blood disorders](#), below).
- **Infusion Reactions:** MabCampath can result in serious, and in some instances fatal, infusion reactions (see [Infusion-related events](#), and **Usual dose**, below)
- **Infections:** Serious, and sometimes fatal, bacterial, viral, fungal, and protozoan infections have been reported in patients receiving MabCampath therapy. PML can occur as the result of a rare and serious brain infection. Your doctor should monitor you for signs or symptoms of this and any infection. (see [Infections](#), below)

What is MabCampath used for?

MabCampath is used for the treatment of patients with previously untreated progressive B-cell chronic lymphocytic leukemia (B-CLL). MabCampath is also used for the treatment of patients with B-CLL when other chemotherapy treatments have been unsuccessful.

B-CLL is a blood cancer affecting a certain type of white blood cells, called B-lymphocytes (B-cells). Patients with B-CLL have too many abnormal lymphocytes, which displace healthy cells in the bone marrow where most new blood cells are formed. This replacement of healthy cells also happens in the blood stream and other organs.

How does MabCampath work?

MabCampath is a monoclonal antibody. Monoclonal antibodies are proteins which specifically recognize and bind to a unique site (called an antigen) on cells. MabCampath binds to an antigen, called CD52, on the surface of B-CLL cells, as well as many normal white blood cells. After binding to cells, MabCampath destroys them, and they are gradually removed from the body as usual.

What are the ingredients in MabCampath?

Medicinal ingredients: The active substance is a monoclonal antibody called alemtuzumab.

Non-medicinal ingredients: The other ingredients are dibasic sodium phosphate, disodium edetate dihydrate, polysorbate 80, potassium chloride, potassium dihydrogen phosphate and sodium chloride. No preservatives are added.

MabCampath comes in the following dosage forms:

MabCampath is a concentrated solution for intravenous administration to be diluted in either 0.9% sodium chloride solution or 5% glucose solution.

MabCampath is provided in single-use vials. MabCampath 30 mg/mL vials contain 30 mg of alemtuzumab in 1 mL of sterile, preservative-free solution. MabCampath is available in boxes of one 30 mg/mL vial (one vial of 30 mg in 1 mL solution) and three 30 mg/mL vials (three vials of 30 mg in 1 mL solution).

Do not use MabCampath if you:

- have an active infection.
- have a weakness of the immune system (e.g., you are HIV positive or have AIDS).
- have or have had a type of rare infection of the brain called progressive multifocal leukoencephalopathy (PML).
- are allergic to MabCampath, to proteins of a similar origin, or to any of the other ingredients listed above under 'non-medicinal ingredients'.
- have another active (second) cancer.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MabCampath. Talk about any health conditions or problems you may have, including if you:

- have had a severe allergic reaction to administration of MabCampath.
- have an active infection.
- have a weakness of the immune system (e.g., you are HIV positive or have AIDS)
- are taking medications that weaken the immune system such as prednisone
- have another active (second) cancer.
- have heart disease.
- are pregnant or plan to become pregnant (see [Pregnancy](#), below).
- are breast-feeding (see [Breast-feeding](#), below).

Other warnings you should know about:

Pregnancy

MabCampath must not be administered to patients who are pregnant. If you are pregnant or you think you may be pregnant, you should tell your doctor immediately. If you are able to get pregnant, then you should avoid becoming pregnant by using two effective contraceptive methods before you start treatment, during treatment, and for 6 months after treatment.

Breast-feeding

MabCampath must not be administered to patients who are breast-feeding. You should stop breast-feeding when you start your treatment. You should not begin breast-feeding until at least three months after you have finished your treatment and you have consulted your doctor.

Blood disorders

Serious, and in some instances, fatal blood disorders have occurred during MabCampath therapy. These include: myelosuppression (a condition that often occurs in chemotherapy that results in fewer platelets, red blood cells, and white blood cells being produced in the bone marrow); autoimmune hemolytic anemia (a condition where antibodies destroy your red blood cells) and autoimmune idiopathic thrombocytopenia (a condition where antibodies destroy your platelets) Your doctor will be carefully monitoring the effects of treatment and your progress by examining you and by taking blood samples on a regular basis.

Because the potential for a fatal reaction to transfusion of any blood products following treatment with MabCampath, it is recommended that you speak to your doctor prior to receiving a blood transfusion.

Infusion Reactions

When you receive MabCampath, you may experience side effects soon after the first infusions. These may include low blood pressure, chills, nausea, fever, shortness of breath, and/or rash. These effects tend to gradually decrease as treatment continues. There is also a remote risk of serious heart problems, including heart attack and irregular heart beat. Your doctor may give you antihistamines (e.g., Benadryl[®]), antipyretics (treatment for fever, e.g., Tylenol[®]), or other medications (e.g. Demerol[®] steroids) to prevent or treat side effects. The dosage of MabCampath will not be increased until the effects are decreased.

Infections

MabCampath treatment may reduce your natural resistance to infections. Therefore, antibiotics may be given to provide you with extra protection.

PML is a condition that causes nerve damage within the brain. You should tell your doctor immediately of any new sign or symptom which may include memory loss, trouble thinking, difficulty with walking

or loss of vision.

Epstein-Barr virus (EBV)

Patients treated with MabCampath have had infections due to a virus called Epstein-Barr virus (EBV), including cases with severe and sometimes fatal liver inflammation. Tell your doctor right away if you have symptoms of infection such as fever, swollen glands, or fatigue.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MabCampath:

Interactions with MabCampath and other medications have not been studied. You should inform your doctor if you are taking or have recently taken any other medications, even those without a prescription, such as vitamins and herbal medicines.

The safety of immunization with any vaccine, particularly live viral vaccines, following therapy with MabCampath has not been studied. The ability of the body to respond to any vaccine following MabCampath has also not been studied. Patients who have recently received MabCampath should not be immunized with live viral vaccines. Speak to your doctor before receiving any vaccinations.

An immune response to MabCampath may interfere with blood tests that use antibodies.

How to take MabCampath:

MabCampath will be given to you by a healthcare professional in a healthcare setting.

Usual dose:

MabCampath is given in the form of a solution directly into the bloodstream through a vein. This is known as an intravenous infusion. Each time you are given MabCampath, it will take about two hours for all the solution to enter your blood.

During the first week, 3 mg of MabCampath is given on Day 1, then 10 mg on Day 3, then 30 mg on Day 5. The dose will be increased as your tolerance for MabCampath improves. This increases the amount of MabCampath you receive slowly, to reduce the possibility of having side effects and allow your body to tolerate MabCampath better. MabCampath will continue to be given at a dose of 30 mg on each of three alternate days each week (that is, 90 mg per week).

MabCampath treatment may continue for up to 12 weeks, depending on your progress.

Overdose:

If you receive more MabCampath than recommended, your doctor will treat you, as appropriate, if you have any side effects. Daily doses greater than 30 mg or total weekly doses greater than 90 mg should not be given, as higher doses have been associated with serious and sometimes fatal reactions. See Warnings and Precautions section above for more details.

Missed Dose:

If your therapy is interrupted for 7 or more days, then your MabCampath therapy will be restarted with gradual dose increases.

What are possible side effects from using MabCampath?

These are not all the possible side effects you may have when taking MabCampath. If you experience any side effects not listed here, tell your healthcare professional.

Like all medicines, MabCampath can have side effects. Your doctor may give you other medicines or change your dosage to help reduce any side effects. You may experience some side effects up to several months following the last dose of MabCampath.

Very common side effects (reported in at least 1 of every 10 patients in clinical trials) that may happen early in your treatment include:

- infections
- fever
- shivering/chills
- sweating
- nausea, vomiting
- low blood pressure
- low white/red blood cell levels
- low blood platelet levels
- tiredness
- rash, itching
- shortness of breath
- headache
- diarrhea
- difficulty breathing
- sleeplessness
- loss of appetite
- pneumonia

Usually, one or more of these effects happen during the first week after the start of treatment. They are usually only mild or moderate and tend to gradually go away and/or improve during the course of treatment.

Pneumonia can occur very commonly during treatment. Your doctor may give you additional antibiotic and/or antiviral treatment to reduce the risk of this and other infections.

Common side effects (reported between 1 and 10 of every 100 patients) include:

Gastrointestinal and liver system: pain in the abdomen, swelling, irritation and/or ulceration of the mouth, abnormal liver function, constipation, indigestion, passing gas, and bleeding in the digestive system (e.g., with tar-like stool).

General disorders: pain, redness or swelling at the site of injection, generally feeling unwell, weakness, pain in various parts of the body (muscle, back, chest, bones, joints), weight loss, dehydration, thirst, excess fluid in the body, low calcium or sodium levels, feeling hot or cold, flu-like symptoms, skin rash, blistering of the skin, confusion, anxiety, depression, and sleepiness.

Heart and blood disorders: high blood pressure, fast or slow heart rate, feeling your heart racing, blood vessel spasm (e.g. angina), becoming red in the face (flushing), bruising of skin, and decreased oxygen in blood, and bluish skin.

Infections: abscess, candida (yeast), herpes and shingles (viral), and respiratory, urinary, gastrointestinal and other bacterial and fungal infections.

Nervous system and special senses: taste changes, decreased sense of touch, dizziness, fainting, sensation of spinning (vertigo), shaking, feeling restless, eye inflammation, and 'pins and needles' or burning sensation of the skin.

Uncommon side effects (reported between 1 and 10 of every 1000 patients) which may be more serious in nature include:

- bone marrow disorders
- heart disorders (heart stopping, heart attack, abnormally fast heart rate)
- stroke
- blood disorders (abnormal clotting, decreased protein, low potassium levels)
- bleeding and inflammation of the gums
- nosebleeds
- fluid in the lungs
- abnormal chest x-ray
- tuberculosis
- lymph gland swelling
- nervousness
- abnormal thinking
- ringing in the ear
- deafness
- hoarseness
- abnormal kidney function
- diabetes, high blood sugar
- impotence
- unsteadiness

- muscle tension/spasm
- blockage of the bowels
- swelling around the eyes
- sensitivity of the skin
- allergic reaction
- a special disorder (called tumour lysis syndrome) which may begin with flank pain and blood in the urine.

One **rare** side effect (called intracranial hemorrhage) is bleeding in the brain.

Serious side effects, including difficulty in breathing, inflammation of the lungs, fainting, heart attack, low red blood cell (anemia) and low blood platelet levels, have occurred. Rarely (in less than 1 in 1000 patients), they have been fatal.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON (occurring in at least 1 of every 10 patients)			
Infections		✓	
High fever		✓	
Shivering/chills		✓	
Nausea		✓	
Vomiting		✓	
Low blood pressure		✓	
Rash		✓	
Itching		✓	
Shortness of breath		✓	
Headache		✓	
Diarrhea		✓	
Difficulty breathing		✓	
Loss of appetite		✓	
COMMON (occurring between 1 and 10 of every 100 patients)			
Bleeding in the digestive system (e.g black tarry stools)		✓	
Skin rash (itchy skin)		✓	
UNCOMMON (occurring between 1 and 10 of every 1000 patients)			
Other abnormal bleeding of any kind		✓	
Allergic reactions		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Fast or irregular heart beat		✓	
Purple-red spots on the skin		✓	
Stroke		✓	
Flank pain and blood in the urine (which may be a sign of tumour lysis syndrome)		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

MabCampath must be refrigerated (2°C to 8°C) and protected from direct sunlight. Do not freeze. DISCARD IF VIAL HAS BEEN FROZEN. Do not use after the expiration date on the vial.

MabCampath contains no preservatives. Once diluted, MabCampath solutions may be stored at room temperature (between 15°C and 30°C) or under refrigeration (between 2°C and 8°C) and must be used within 8 hours. MabCampath solutions should be protected from light.

Keep out of reach and sight of children.

If you want more information about MabCampath:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

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