PART III: CONSUMER INFORMATION

[Pr]MabCampath® (pronounced **'mabCAMpath')**
(Alemtuzumab)

This leaflet is part III of a three-part Product Monograph published when MabCampath was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about MabCampath. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is 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.

What it does:
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.

When it should not be used:
You should not be given 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 below under 'non-medicinal ingredients'.
- have another active (second) cancer.

What the medicinal ingredient is:
The active substance is a monoclonal antibody called alemtuzumab.

What the important nonmedicinal ingredients are:
The other ingredients are dibasic sodium phosphate, disodium edetate dihydrate, polysorbate 80, potassium chloride, potassium dihydrogen phosphate and sodium chloride. No preservatives are added.

What dosage forms it comes in:
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).

WARNINGS AND PRECAUTIONS

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)

BEFORE you use MabCampath talk to your doctor 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).

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.

INTERACTIONS WITH THIS MEDICATION

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.

PROPER USE OF THIS MEDICATION

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect		Talk with your doctor	
		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		✓
	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)		✓

This is not a complete list of side effects. If you experience any unexpected effects while taking MabCampath, contact your doctor.

How to Store It:

MabCampath must be refrigerated (2ºC to 8ºC) 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 15ºC and 30ºC) or under refrigeration (between 2ºC and 8ºC) and must be used within 8 hours. MabCampath solutions should be protected from light.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

Online: www.healthcanada.gc.ca/medeffect
Toll free phone: 1-866-234-2345
Complete a Canada Vigilance Reporting Form and:
Fax toll free fax: 1-866-678-6789 or
Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at www.sanofi.ca or by contacting Sanofi Genzyme at: 1-877-220-8918.

This leaflet was prepared by: Sanofi Genzyme, a division of sanofi-aventis Canada Inc.

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