

MABCAMPATH®

Alemtuzumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MabCampath.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MabCampath against the benefits they expect it will have for you.

Keep this leaflet.

You may need to read it again.

What MabCampath is used for

This medicine is an anti-cancer drug used to treat a form of leukaemia known as B-cell chronic lymphocytic leukaemia (B-CLL). This is a cancer of the type of white blood cells called lymphocytes.

Patients with B-CLL have too many abnormal lymphocytes, which displace healthy cells in the bone marrow (where most new blood cells are formed) in addition to the blood stream and other organs. Without enough healthy blood cells, infections, anaemia, bruising, excessive bleeding or even organ failure can result.

MabCampath is a monoclonal antibody that specifically recognises and binds to a unique protein located on the surface of abnormal lymphocytes. After binding, MabCampath destroys the abnormal lymphocytes, which are then

gradually removed from the body by normal biological processes.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is not enough information to recommend the use of this medicine for children.

There is not enough information to recommend the use of this medicine in patients who have kidney or liver disorders.

Before you are given MabCampath

When you must not be given it

Do not take MabCampath if you have an allergy to:

- any medicine containing alemtuzumab or murine proteins
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not have MabCampath if you have any of the following medical conditions:

- an active infection which is spread around the body
- HIV
- an active secondary cancer

Do not take medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine. Do not begin breast-feeding again until at least 4 weeks after you have finished your treatment and after you have consulted your doctor.

It is possible that your baby may be affected if you breast-feed.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had heart disease, chest pains and/or are receiving treatment to reduce high blood pressure.

As MabCampath may make these conditions worse, your doctor will need to monitor you carefully.

Tell your doctor if you have been treated in the past with chemotherapies or general medications that may have a high risk of causing heart damage.

Your doctor may wish to monitor your heart function whilst receiving this medicine.

If you have not told your doctor about any of the above, tell him/her before you are given MabCampath.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

Some medicines and MabCampath may interfere with each other.

These include:

- Anti-cancer agents. It is recommended that MabCampath is not given within 3 weeks of other chemotherapeutic agents.
- Live viral vaccines. It is recommended that patients do not receive live viral vaccines at least 12 months following MabCampath therapy.

There medicines may be affected by MabCampath or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Speak to your doctor before receiving any vaccinations.

Your doctor may have more information on medicines to be careful with or avoid while taking this medicine.

How MabCampath is given

MabCampath is given under the supervision of a specialist doctor experienced in the treatment of your disease.

MabCampath is given in the form of a solution directly in to the blood stream through a vein. This is known as intravenous infusion. Each time you are given MabCampath, it will take about 2 hours for all the solution to enter your blood.

How much is given and when

During the first week, 3 mg of MabCampath in the solution is given on Day 1, then 10 mg on Day 2 and then 30 mg on Day 3. MabCampath will continue to be given at 30 mg on each of 3 alternate days each week.

You may experience early side effects and the initial smaller doses may be repeated until the effects go away or reduce. The idea is to increase amounts of MabCampath slowly to reduce the possibility of having side effects and allow your body to tolerate it better. The doctor will carefully monitor you and decide what are the appropriate amounts of MabCampath to give during your treatment period.

For how long is it given

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

If you are given too much (overdose)

The doctor will treat you as appropriate if you have any ill effects from having been given too much of MabCampath.

In cases of overdose, it is advisable to contact the Poisons Information Centre (Australia: 13 11 26; New Zealand: 0800 POISON or 0800 764 766) for recommendations on the management of overdoses.

Symptoms of an overdose may include a severe fever, tiredness, headaches, being short of breath when exercising, dizziness and looking pale.

While you are using MabCampath

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MabCampath

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are a fertile male or female of childbearing potential, ensure that you use reliable form of birth control during treatment and for at least 6 months after treatment. If you do become pregnant while taking this medicine, tell your doctor immediately.

The effects of this medicine on reproduction are unknown.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Some side effects (for example, blood disorders) can only be found when your doctor does tests on a regular basis. If you have pre-existing medical conditions (such as heart disease or chest pains and/or you are receiving treatment to reduce high blood pressure) your doctor will monitor you carefully as MabCampath may make these conditions worse.

Take all medications as prescribed by your doctor.

MabCampath causes suppression of the immune system, which affects the natural ability of the body to fight infection for up to six months after treatment. Therefore, you may require antibiotics and antivirals to provide you with extra protection until your immune system has recovered.

Your doctor may also prescribe other additional medication to help alleviate possible side effects.

Things to be careful of

Be careful driving or operating machinery until you know how MabCampath affects you.

Confusion and sleepiness have been reported with this medicine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking MabCampath.

This medicine helps most people with B-cell chronic lymphocytic leukaemia (B-CLL), but is may have unwanted side effects. All medicines can have side effects. Sometimes we are serious, most of the time they are not.

The side effects mentioned below are usually due to MabCampath because it affects the body's immune system in general and reduces resistance to infection. Some infections may be serious and sometimes fatal.

Your doctor may give you other medicines or change your dosage to help reduce any side effects. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following list of side effects. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- discharge with itching of the eyes and crusty eyelids
- bleeding or bruising more easily than normal
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- weight decreased, loss of appetite
- anxiety, confusion, depression, drowsiness, trouble sleeping, unusually overactive
- fainting, dizziness
- tremor, pins and needles, decreased feeling or sensitivity, headache, taste loss
- bluish discoloration of skin, flushing
- abnormal heart beat (fast or slow)
- difficulty in breathing, chest tightness, coughing,

- nausea, vomiting, stomach pain, diarrhoea, indigestion, constipation, wind
- rash (itchy or not), excessive sweating, redness of the skin
- aching muscles, muscle tenderness or weakness (not caused by exercise), back pain, joint pain, chest pain
- fever, chills, tiredness, unusual weakness
- feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell
- sore throat and discomfort when swallowing
- symptoms of low calcium levels in the blood which includes muscle spasm or twitching, numbness or tingling in fingers and toes, depression, irritability, confusion, disorientation
- dehydration or excessive thirst
- blisters and/or ulcers in the mouth or genitalia
- symptoms of pneumonia such as fever, chills, shortness of breath, cough and phlegm that may be blood stained
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- burning or pain upon urination, increased frequency to urinate
- sore, creamy-yellow, raised patches in the mouth
- itching, burning and a thick, white, "cottage cheese" discharge

The above list includes the more common side effects of your medicine. They are often mild or moderate problems that are short-lived and diminish during the course of treatment. **However, if you believe the side effect is of a more severe nature, tell your doctor as soon as possible.**

Tell your doctor as soon as possible if you notice any of the following:

- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- unusually swollen glands in the neck, armpit or groin
- loss of hearing
- loss of control of your bladder or bowels

The above list includes serious side effects that may require medical attention. Serious side effects are usually uncommon or rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- signs of heart attack such as central crushing chest pain, pain in left arm, increased sweating
- signs of tumour lysis syndrome such as pain in one side of the body under the rib cage, little or no urine, drowsiness, nausea, vomiting, breathlessness, irregular heart beat, loss of memory, loss of consciousness
- signs of Guillain-Barre syndrome, which is a temporary inflammation of the nerves, causing pain, weakness, and paralysis in the extremities and often progressing up to the chest and face
- abnormally fast or irregular heart beat
- extreme difficulty breathing, shortness of breath, sharp chest pains which are worse when breathing in, frequent fainting
- severe bleeding or bruising more than usual (e.g. persistent nose bleeds)
- signs of intracranial haemorrhage such as severe headache, nausea and vomiting, alertness changes, problems with speech, balance,

coordination or focusing the eyes.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are usually uncommon or rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Keep all doctors appointments so your progress can be checked.

Some side effects (for example, blood disorders) can only be found when your doctor does tests on a regular basis.

After Using MabCampath

Storage

MabCampath will be stored by your doctor. Storage conditions are outlined below for your information.

MabCampath vials: Store at 2-8°C (in a refrigerator). Do not freeze. Protect from light.

MabCampath reconstituted solution:

Should be used immediately after dilution or within 8 hours after dilution. Solutions may be stored at 15-30°C or refrigerated. This can only be accepted if preparation of the solution takes place under strictly aseptic conditions and the solution is protected from light.

MabCampath contains no antimicrobial preservative.

vial contains 1 mL colourless to slightly yellow concentrate.

Ingredients

Each MabCampath vial contains 30 mg of alemtuzumab as the active ingredient, which is equivalent to 1 mL of a 30 mg/mL solution.

It also contains:

- disodium edentate
- phosphate buffered saline. This consists of polysorbate 80, potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate and water for injections to make up 1 mL

Sponsor

Genzyme Australasia Pty Ltd
Level 1, Building C
12-24 Talavera Road
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Product Description

What it looks like

MabCampath is diluted for administration via intravenous drip. Each pack of MabCampath contains three 2 mL clear glass vials. Each