

Mabcampath

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I receiving Mabcampath?

Mabcampath contains the active ingredient alemtuzumab. Mabcampath is 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.

For more information, see Section [1. Why am I receiving Mabcampath?](#) in the full CMI.

2. What should I know before I receive Mabcampath?

Do not use if you have ever had an allergic reaction to alemtuzumab, other murine proteins or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I receive Mabcampath?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mabcampath and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I receive Mabcampath?

- Mabcampath is given via infusion into the blood. Each time you are given Mabcampath it will take about 2 hours.
- During the first week, 3 mg of Mabcampath is given on Day 1, then 10 mg on Day 2 and 30 mg on Day 3
- Mabcampath will continue to be given at 30 mg doses on 3 alternate days each week

More instructions can be found in Section [4. How do I receive Mabcampath?](#) in the full CMI.

5. What should I know while receiving Mabcampath?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are receiving Mabcampath.• If you are a fertile male or female of childbearing potential, ensure that you are using reliable birth control during treatment and for at least 6 months after treatment.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Mabcampath affects you• Confusion and sleepiness have been reported with this medicine
Looking after your medicine	<ul style="list-style-type: none">• Mabcampath will be stored by your doctor or pharmacist

For more information, see Section [5. What should I know while receiving Mabcampath?](#) in the full CMI.

6. Are there any side effects?

Common side effects include bleeding or bruising more easily than normal, tiredness, headaches, weight loss, loss of appetite, fainting, dizziness, tremor, pins and needles, headache, nausea, vomiting, fever, aching muscles, diarrhoea, constipation.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Mabcampath

Active ingredient(s): *alemtuzumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mabcampath. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mabcampath.**

Where to find information in this leaflet:

- [1. Why am I receiving Mabcampath?](#)
- [2. What should I know before I receive Mabcampath?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I receive Mabcampath?](#)
- [5. What should I know while receiving Mabcampath?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I receiving Mabcampath?

Mabcampath contains the active ingredient alemtuzumab. Mabcampath is a monoclonal antibody that specifically recognises and binds to a unique protein located on the surface of abnormal lymphocytes.

Mabcampath 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 organ failure can result.

2. What should I know before I receive Mabcampath?

Warnings

Do not use [medicine name] if:

- you are allergic to to alemtuzumab or murine proteins, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions including:
 - an active infection which is spread around the body
 - HIV
 - an active secondary cancer
 - heart disease or condition - your doctor will monitor you carefully as Mabcampath may make these conditions worse

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not receive treatment with Mabcampath if you are pregnant. It may affect your developing baby if you receive this medicine whilst pregnant. Ensure you are using reliable contraception during treatment and for 6 months after treatment.

If you become pregnant whilst receiving this medicine inform your doctor immediately.

Do not breastfeed if you are receiving Mabcampath. Do not begin to breastfeed until at least 4 weeks after you have finished your treatment with Mabcampath and have consulted your doctor. It is possible that your baby might be affected if you breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Mabcampath and affect how it works. These include

- anti-cancer medicines. It is recommended that Mabcampath is not given within 3 weeks of other chemotherapeutic medicines
- live viral vaccines. It is recommended that patients do not receive live viral vaccines for at least 12 months following Mabcampath therapy

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect [medicine name].

4. How do I receive Mabcampath?

How much is given and when

- Mabcampath is given under the supervision of your doctor
- It is given in the form of a solution directly into the bloodstream through a vein, known as an intravenous infusion
- Each time you receive Mabcampath the infusion will take about 2 hours

- During the first week, 3 mg of Mabcampath will be given on Day 1, then 10 mg on Day 2 and 30 mg on Day 3. Mabcampath will continue to be given at 30 mg doses on 3 alternate days each week
- You may experience early side effects and the initial smaller doses may be repeated until the side effects go away or reduce. The aim is to increase the amounts of Mabcampath you receive slowly in order to reduce the possibility of side effects and to enable your body to tolerate the medicine better
- Your doctor will carefully monitor you and decide how much to give you throughout your treatment with Mabcampath

How long is Mabcampath given for?

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

Mabcampath causes suppression of the immune system, which affects the natural ability of the body to fight infection for up to 6 months after treatment. Therefore, you may require antibiotics or antivirals to provide you with extra protection until your immune system has recovered.

If you receive too much Mabcampath

If you think that you have been given too much Mabcampath, you may need urgent medical attention.

Your doctor will treat you as required if you have any ill effects from having received too much Mabcampath.

You should immediately:

- phone the Poisons Information Centre
(by calling 13 11 26)

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while receiving Mabcampath?

Things you should do

Remind any doctor or dentist you visit that you are receiving Mabcampath.

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

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

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mabcampath affects you.

Mabcampath may cause confusion and sleepiness in some people.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● 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, looking pale● weight loss, loss of appetite● anxiety, confusion, depression, drowsiness, trouble sleeping, being unusually overactive● fainting, dizziness	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>If you believe the side effect is of a more severe nature, tell your doctor as soon as possible.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● 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, pressure, 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 	

Less serious side effects	What to do
<p>throbbing ache, fever, stuffy nose and loss of the sense of smell</p> <ul style="list-style-type: none"> ● 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 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● 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 ● unexplained weight gain, feeling cold, worsening tiredness, new constipation ● weight loss, excessive sweating, intolerance to heat, increased bowel movements 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● unusually swollen glands in the neck, armpit or groin ● loss of hearing ● loss of control of your bladder or bowel ● 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, aching sensation in your chest or arms that may spread to your neck, jaw or back, pain in left arm, increased sweating ● signs of a stroke such as drooping of the skin on your face or sudden weakness or numbness on one side of the body or sudden difficulty with speech or your vision 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 haemophagocytic lymphohistiocytosis (excessive activation of white blood cells) such as fever, swollen glands, bruising, or skin rash. Haemophagocytic lymphohistiocytosis can be fatal if not diagnosed and treated early ● signs of glomerulonephritis such as pink or cola-coloured urine, or foam in the urine, or noticeable swelling face, hands, feet and abdomen ● signs of Guillain-Barre syndrome, which is a 	

Serious side effects	What to do
<p>temporary inflammation of the nerves, causing pain, weakness, and paralysis in the extremities and often progressing up to the chest and face</p> <ul style="list-style-type: none"> ● signs of hepatitis (associated with a viral infection called Epstein-Barr Virus) including fatigue, flu-like symptoms, dark urine, pale stool, abdominal pain, loss of appetite, unexplained weight loss, yellow skin and eyes ● 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) 	

Serious side effects	What to do
<ul style="list-style-type: none"> • signs of intracranial haemorrhage such as severe headache, nausea, vomiting, alertness changes, problems with speech, balance, coordination or focusing of the eyes 	

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Mabcampath contains

Active ingredient (main ingredient)	alemtuzumab
Other ingredients (inactive ingredients)	disodium edentate phosphate buffered saline. This consists of polysorbate 80, potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate and water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Mabcampath looks like

Mabcampath is a colourless to slightly yellow concentrate. (AUST R 116622).

Mabcampath, when reconstituted, should be used immediately after dilution or within 8 hours after dilution, The solution should be stored between 15°C and 30°C or refrigerated. Preparation of the solution should occur under aseptic conditions and the solution should be protected from light.

Mabcampath contains no antimicrobial preservative.

Who distributes Mabcampath

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

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