



Patient guide and diary

A guide for people with
minimal residual disease positive (MRD+)
B-cell precursor acute lymphoblastic leukaemia (ALL)





MRD AND BLINCYTO®

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INTRODUCTION

Your doctor has prescribed you BLINCYTO[®], so you probably have some questions such as:

What is this treatment?

How is it different to other treatments I have had?

What should I expect during treatment?

This guide will help answer some of your questions, and explain what treatment with BLINCYTO[®] may be like for you. It also includes a diary to track your progress and to write down any side effects or questions you may have for your healthcare team.

However, if you are unsure about anything, please ask your healthcare team, or consult the BLINCYTO[®] Consumer Medicine Information.

WHAT IS MRD-POSITIVE ACUTE LYMPHOBLASTIC LEUKAEMIA?

By now you will already have received treatment for your acute lymphoblastic leukaemia or ALL. Cancer can often hide from treatments, making it hard to completely eliminate. Even after achieving remission with chemotherapy, a small number of cancer cells can remain in your body. This is called minimal residual disease or MRD. Your doctor has very sensitive tests that can detect MRD. When MRD is detected, it is known as MRD-positive ALL.¹

Your doctor's goal is for you to become MRD-negative, which means you do not have detectable traces of cancer left.¹

WHAT IS BLINCYTO[®]?

BLINCYTO[®] is used to treat detectable traces of disease, otherwise known as MRD-positive disease.^{2,3}

BLINCYTO[®] is not a chemotherapy drug.² It is a type of immunotherapy that engages your own immune system to help fight your cancer.²

BLINCYTO[®] works along with your immune system to help your white blood cells find, attack and destroy any cancer cells remaining after chemotherapy.

GETTING STARTED

Designing your treatment plan

Before you start BLINCYTO®, your healthcare team will design a treatment plan specifically for you.

Make sure to talk to your doctor:³

- If you have any allergies to any other medicines, foods, preservatives or dyes
- If you have ever had any of the following medical conditions:
 - Neurological problems (such as seizures, memory loss, confusion, disorientation, loss of balance or difficulty in speaking)
- If you have an active infection
- If you have ever had an infusion reaction after previously using BLINCYTO®
- If you are pregnant, think you are pregnant, or plan to become pregnant
 - The effects of BLINCYTO® in pregnant women are not known
 - Women who might become pregnant should use contraception during treatment. You must also do this for 48 hours after your last treatment. Talk to your doctor or nurse about suitable methods of contraception
- If you are breastfeeding or planning to breastfeed
 - It is not known whether BLINCYTO® passes into breast milk
 - You should not breastfeed during treatment with BLINCYTO® and for at least 48 hours after your last treatment
- If you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop
- If you think you may need any vaccinations in the near future, including those needed to travel to other countries
 - Some vaccines must not be given within two weeks before, at the same time as or in the months after you receive treatment with BLINCYTO®. Your doctor will check if you should have the vaccination.

HOW IS BLINCYTO® GIVEN?³

BLINCYTO® is given to you through a vein (intravenous) continuously for 4 weeks by an infusion pump. Either an infusion bag or cassette will be used to hold the medication.

Your doctor will determine how often your BLINCYTO® infusion bag or cassette will be changed, which may range from every day to every 4 days. The infusion rate may be faster or slower depending on how often the bag or cassette is changed.

YOUR TREATMENT CYCLE

One treatment cycle of BLINCYTO® lasts for 4 weeks of continuous treatment by an infusion pump, followed by a 2-week break with no BLINCYTO® infusions.

After one cycle of BLINCYTO®, your doctor will assess your response. Your doctor may then decide to give you another one to three additional cycles of BLINCYTO®.



After the 2-week break, your doctor will decide whether you will be given additional treatment cycles of BLINCYTO®.

WHERE WILL YOU BE TREATED?³

To monitor you for side effects, it is recommended that you at least begin your treatment with BLINCYTO[®] as an in-patient in a hospital or clinic.

Your doctor will decide what is best for you. You may be asked to stay in hospital for approximately:

- The first 3 days of your first treatment cycle
- The first 2 days of your second treatment cycle



If you receive additional treatment cycles, or if your treatment is stopped for 4 or more hours, you may also be treated in a hospital or clinic in order to be supervised by your healthcare team.²

Depending on your treatment plan, your doctor may allow you to continue treatment with BLINCYTO[®] at:



MEDICINES GIVEN BEFORE EACH TREATMENT CYCLE³

Before your treatment with BLINCYTO[®], you will be given other medicines (premedication) to help reduce potential reactions to BLINCYTO[®] and a potentially life-threatening complication known as tumour lysis syndrome, which is caused when large numbers of cancer cells are rapidly killed by your treatment. These medicines may include steroids.²

INFUSION PUMP AND INTRAVENOUS TUBING³

You will have the pump connected to you 24 hours a day for 28 days. Your healthcare team will advise you on how to manage your daily activities around your infusion pump.

- ✓ Make sure the tubing stays connected to the pump at all times.
- ✗ Do not let the tubing become tangled or twisted at any time.
- ✗ Do not lie on the tubing.
- ✗ Do not change the pump settings on purpose.
- ✗ Do not pull the tubing or unplug the pump at any time.
- ✓ Contact your healthcare team immediately if you notice blood in the tubing.
- ✓ Keep the pump, the tubing and the covering at the site where it is inserted into your vein dry at all times.
- ✓ Contact your healthcare team if you have any concerns regarding how your pump is working.

The number of treatment cycles and the dose that you will be given will depend on how well you tolerate and respond to BLINCYTO[®]. Your doctor will discuss with you how long your treatment will last. Your treatment may be interrupted depending on how well you tolerate BLINCYTO[®].

THINGS YOU MUST DO DURING TREATMENT³

- ✓ **Keep the area around the catheter clean if you have a catheter for infusion.**

This is very important, otherwise you could get an infection. Your healthcare team will show you how to care for your catheter site.

- ✓ **If there is a problem with your infusion pump or your pump alarm sounds, contact your healthcare team immediately but do not adjust the settings on the pump unless directed to do so.**

Any changes to the pump settings may result in a dose that is too high or too low.

- ✓ **Contact your healthcare team immediately:**
 - If there is a problem with the pump or if the pump alarm sounds
 - If you think you may have been given more BLINCYTO[®] than you should
 - If the infusion pump stops unexpectedly. Do not try to restart your pump

Do not drive, use heavy machines, or engage in hazardous activities while you are being given BLINCYTO[®]. BLINCYTO[®] can cause problems such as dizziness, seizures and confusion.³

HOW SHOULD BLINCYTO[®] BE STORED?³

BLINCYTO[®] solution for infusion will be prepared by your pharmacist and stored in a refrigerator at 2°C to 8°C until infusion.

Once at room temperature (up to 25°C), your pump will be set up to deliver the solution in no more than 96 hours.

Ask your healthcare team about disposing of BLINCYTO[®] and used supplies.

POSSIBLE SIDE EFFECTS³

All medicines can have side effects. Some side effects are more serious than others and may require medical attention.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your healthcare team or pharmacist if you notice any of the following:

- Tingling skin
- Rapid heart rate
- Cough, nausea, constipation, diarrhoea, stomach pain, vomiting
- Back pain, pain in hands or feet, painful/swollen joints, bone pain
- Rash
- Swollen hands, ankles or feet
- Tiredness
- Weight gain
- Flushing

The above list includes the more common side effects of BLINCYTO®.

Tell your doctor immediately if any of the following happen:

- Fever, swelling or chills, shortness of breath, headache and dizziness, any of which may become severe
- Difficulty sleeping (insomnia)
- Confusion, disorientation
- Headache, shaking (tremor), dizziness
- Difficulty in speaking, communicating, thinking or processing thoughts, or remembering things
- Seizures (convulsions)
- Chest pain
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

The above list includes signs and symptoms of potentially serious side effects that may require urgent medical attention or hospitalisation.

Tell your healthcare team as soon as possible if you do not feel well while you are being given BLINCYTO®. Ask your healthcare team to answer any questions you may have.

IMPORTANT THINGS TO REMEMBER WHILE RECEIVING BLINCYTO®³

Tell your doctor, nurse or pharmacist that you are receiving BLINCYTO® before you start any new medicine.

Tell any other doctors who treat you that you are receiving BLINCYTO®.

Tell your doctor, nurse or pharmacist immediately if you experience any of the following while being treated with BLINCYTO®:

- **Seizures, difficulty in speaking or slurred speech, confusion and disorientation, or loss of balance**
- **Chills or shivering, or feel warm**
Take your temperature as you may have a fever – these may be symptoms of an infection
- **A reaction at any time during your infusion**
Symptoms may include dizziness, face swelling, difficulty breathing, wheezing, or rash
- **Severe and persistent stomach pain, with or without nausea and vomiting**
These may be symptoms of a serious and potentially fatal condition known as pancreatitis (inflammation of the pancreas).

The reaction may have to be treated and your dose of BLINCYTO® may need to be adjusted.

Your doctor or nurse will monitor you for signs and symptoms of these reactions.

You may experience a severe low white blood cell count or severe low white blood count with fever (neutropaenia or febrile neutropaenia) or elevated liver enzymes.

Your doctor or nurse will take regular blood tests to monitor your blood counts during treatment with BLINCYTO®.



MY TREATMENT RESOURCES

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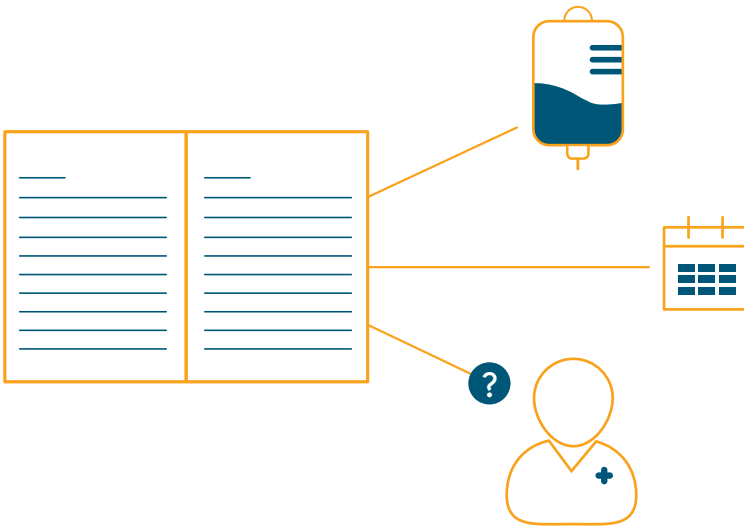


MY TREATMENT DIARY

Being diagnosed with a condition like ALL can feel overwhelming at times. Many patients have found it helpful to use a diary to help track information such as their treatment schedule and any issues related to their condition and its treatment.

As you begin your treatment with BLINCYTO®, you can use this diary to track your progress and to write down any side effects or questions you may have for your healthcare team. The diary is also a good place to record details of other medicines you are taking whether prescribed by a doctor or bought from a pharmacy, supermarket or health food shop.

It is a good idea to take your diary to all your medical appointments so you can share this information with all your healthcare professionals. The more information you can share with your healthcare team, the better equipped you should be to discuss your condition and its treatment with BLINCYTO®.



MY HEALTHCARE TEAM

Record the contact details of your healthcare team here. This might include your haematologist or oncologist, your haematology nurse and general practitioner (GP).

Healthcare professional:

Name:

Address:

Postcode:

Telephone:

Email:

Healthcare professional:

Name:

Address:

Postcode:

Telephone:

Email:

Healthcare professional:

Name:

Address:

Postcode:

Telephone:

Email:

Healthcare professional:

Name:

Address:

Postcode:

Telephone:

Email:

MY BACKGROUND HEALTH INFORMATION

Do you have any other health problems that you are aware of?

Are you currently taking any medication for other health problems?

Do you have any allergies?

MY TREATMENT WITH BLINCYTO®

This tool will help you stay organised on your treatment journey. Use this calendar to keep track of scheduled appointments and bag changes. The next time you meet with your healthcare team, have this calendar with you. They can help you fill it out or answer any questions you may have.

1. Simply fill in the months and dates in the blank spaces below.
2. Mark the day you start your BLINCYTO® treatment.
3. Then count out when your bag change will occur: 1 day, 2 days, 3 days or 4 days. For example, if you get a 2-day bag on Tuesday, your bag change is on Thursday. Write it down!

Month

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Month

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Month

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Month

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Month

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

MY MEDICAL APPOINTMENTS

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

MY MEDICAL APPOINTMENTS

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

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Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

MY MEDICAL APPOINTMENTS

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

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Purpose: _____

Notes: _____

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

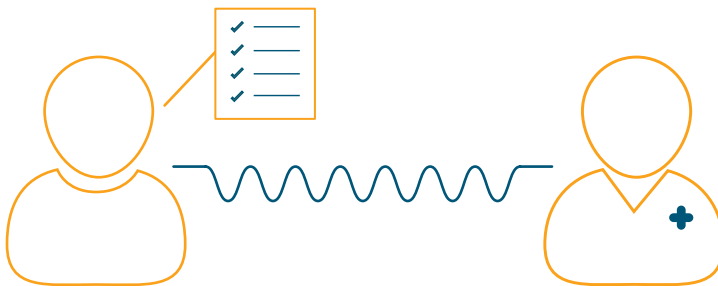
A REMINDER OF WHEN TO CONTACT YOUR HEALTHCARE TEAM³

Tell your doctor, nurse or pharmacist immediately if you experience any of the following while being treated with BLINCYTO[®]:

- **Seizures, difficulty in speaking or slurred speech, confusion and disorientation, or loss of balance**
- **Chills or shivering, or feel warm.**
Take your temperature as you may have a fever – these may be symptoms of an infection
- **A reaction at any time during your infusion.**
Symptoms may include dizziness, face swelling, difficulty breathing, wheezing, or rash.
- **Severe and persistent stomach pain, with or without nausea and vomiting.**
These may be symptoms of a serious and potentially fatal condition known as pancreatitis (inflammation of the pancreas)
The reaction may have to be treated and your dose of BLINCYTO[®] may need to be adjusted.
Your doctor or nurse will monitor you for signs and symptoms of these reactions.

You may experience a severe low white blood cell count or severe low white blood count with fever (neutropaenia or febrile neutropaenia) or elevated liver enzymes.

Your doctor or nurse will take regular blood tests to monitor your blood counts during treatment with BLINCYTO[®].



IF YOU WOULD LIKE MORE INFORMATION ABOUT BLINCYTO[®], TALK WITH YOUR HEALTHCARE TEAM.

Alternatively, for more information on BLINCYTO[®] or to report an adverse event involving BLINCYTO[®], please contact Amgen Medical Information on 1800 803 638

References: **1.** Leukaemia Foundation. Acute lymphoblastic leukaemia (ALL) in adults. A guide for patients and families. June 2015. Available at: www.leukaemia.org.au/. Accessed February 2020. **2.** BLINCYTO[®] (blinatumomab) Product Information. www.amgen.com.au/Blincyto.PI. **3.** BLINCYTO[®] (blinatumomab) Consumer Medicine Information. www.amgen.com.au/Blincyto.CMI.

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AU-12689. AMG3516. Prepared February 2020.