

STARTING BLINCYTO[®]

A guide for adult patients with
Philadelphia chromosome-negative
relapsed or refractory B-cell precursor
acute lymphoblastic leukaemia (ALL)

 **BLINCYTO[®]**
(blinatumomab)



Fictitious patient

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 is here to help answer some of your questions, and explain what treatment with BLINCYTO[®] may be like for you. However, if you are unsure about anything, please ask your healthcare team, or consult the Consumer Medicine Information and the Educational Brochure for Patients and Caregivers.

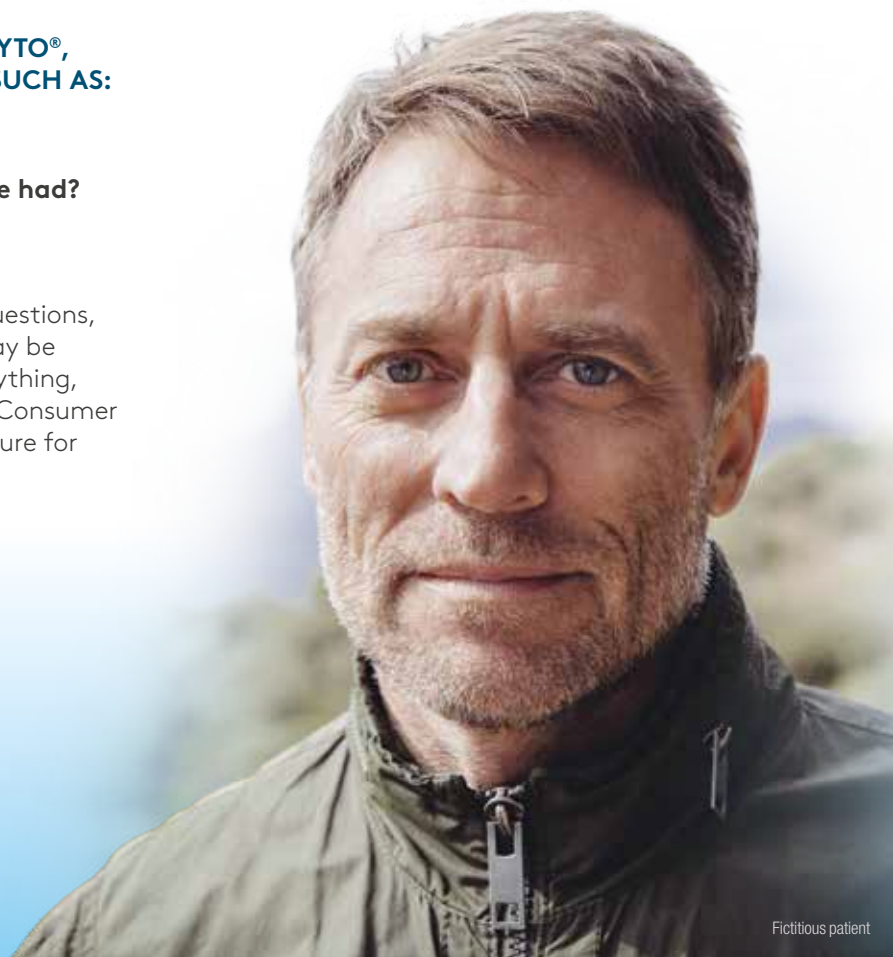


TABLE OF CONTENTS

WHAT IS ACUTE LYMPHOBLASTIC LEUKAEMIA?	4
WHAT IS BLINCYTO®?	4
GETTING STARTED	
Designing your treatment plan.....	6
How is BLINCYTO® given?.....	8
Things you must do during treatment.....	11
POSSIBLE SIDE EFFECTS	12
IMPORTANT THINGS TO REMEMBER WHILE TAKING BLINCYTO®	14
PATIENT CARD	15

WHAT IS ACUTE LYMPHOBLASTIC LEUKAEMIA?

Acute lymphoblastic leukaemia, or ALL, is a cancer of the blood in which a particular kind of white blood cell grows out of control.¹

Many patients achieve remission after they are first treated for ALL.¹ That means that all signs and symptoms of cancer have disappeared.¹ But sometimes, cancer cells can return after a patient is treated and cause a relapse.¹

In other cases, a patient may be treated and never reach remission; this is referred to as refractory disease.¹

WHAT IS BLINCYTO®?

BLINCYTO® is used to treat adults with a type of ALL called Philadelphia chromosome-negative (Ph-) B-cell precursor ALL, who have tried other treatments and didn't reach remission or who relapsed.²

BLINCYTO® is not a chemotherapy drug.² It is a type of immunotherapy that helps your own immune system fight your cancer.²

BLINCYTO® works by enabling your immune system to attack and destroy the abnormal white blood cancer cells found in ALL.³



DID YOU KNOW?

Relapse means that the leukaemia has re-appeared. Although the majority of people treated for ALL will achieve a remission, a significant proportion will relapse over time.¹

Resistant or refractory disease means that the leukaemia is not responding to treatment. This happens in around 20% of people with ALL.¹



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 about:³

- Any allergies you have 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 are able to 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 when 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 lasts for 4 weeks, followed by a 2-week break with no BLINCYTO® infusions.



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

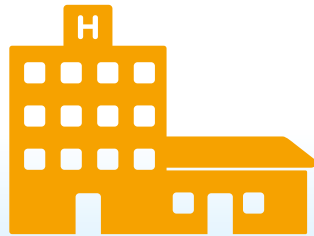
WHERE WILL YOU BE TREATED?

To monitor you for side effects, it is recommended that you receive BLINCYTO® 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 9 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:



An outpatient Clinic



Your home

MEDICINES GIVEN BEFORE EACH TREATMENT CYCLE

Before your treatment with BLINCYTO[®], you will be given other medicines (pre-medication) to help reduce reactions to BLINCYTO[®] and a potentially life-threatening complication known as tumour lysis syndrome, which is caused by chemical disturbances in the blood due to the breakdown of dying cancer cells. These medicines may include steroids.²

INFUSION PUMP AND INTRAVENOUS TUBING

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?

BLINCYTO[®] solution for infusion will be prepared by your pharmacist and stored in a refrigerator at 2°C to 8°C until infusion.³

Once at room temperature (up to 25°C), your pump will be set up to deliver the solution in no more than 96 hours.³

Ask your healthcare team about disposing of BLINCYTO[®] and used supplies.³

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.
- Rash
- Back pain, pain in hands or feet, painful/swollen joints, bone pain
- Swollen hands, ankles or feet
- Tiredness
- Weight gain.

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 (neutropenia or febrile neutropenia) or elevated liver enzymes.

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



PATIENT CARD

Because ALL is a serious condition, it's important for you to have quick and easy access to your medical contacts and information. Here is a patient card that you should fill out and keep handy at all times.

PATIENT CARD

Please show this card to all emergency and healthcare providers.

Information about BLINCYTO® (blinatumomab)

My name is

I am being treated with BLINCYTO®, a treatment for acute lymphoblastic leukaemia, which can lower my immune system.

I started treatment on

Before any treatment, please call my prescribing doctor at the number below. If any medical evaluations are undertaken, please provide copies of all medical records, including any treatments and/or test results, to the doctor(s) named below.

	Name	Hospital	Phone Number
Haematologist			
Haematology Nurse			

For more information on BLINCYTO® or to report any adverse events or product complaints involving BLINCYTO® please contact Amgen Australia Medical Information on 1800 803 638.

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

For more information on BLINCYTO[®] or to report an adverse event involving BLINCYTO[®] please contact Amgen Australia 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 October 2016. **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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