



Information guide and diary

For parents/carers of children with
minimal residual disease (MRD) positive
acute lymphoblastic leukaemia (ALL)





MRD AND BLINCYTO®

TABLE OF CONTENTS

MRD AND BLINCYTO®

WHAT IS MRD-POSITIVE ACUTE LYMPHOBLASTIC LEUKAEMIA?	3
WHAT IS BLINCYTO®?	3
STARTING BLINCYTO® THERAPY	4
HOW IS BLINCYTO® GIVEN	5
POSSIBLE SIDE EFFECTS OF BLINCYTO®	9
IMPORTANT THINGS TO REMEMBER WHILE YOUR CHILD IS TAKING BLINCYTO®	10
QUESTIONS TO ASK YOUR CHILD'S DOCTOR ABOUT BLINCYTO®	11
RETURNING HOME AND GOING BACK TO SCHOOL	12
EXPLAINING BLINCYTO® TO YOUNG CHILDREN	13

INTRODUCTION

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

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

What is this treatment?

How is it different to other treatments my child has had?

What should I expect during treatment?

WHAT IS MRD-POSITIVE ACUTE LYMPHOBLASTIC LEUKAEMIA?

By now your child will already have received treatment for their acute lymphoblastic leukaemia or ALL. But 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 this body. This is called minimal residual disease or MRD. Your child's doctor has very sensitive tests that can detect MRD. When MRD is detected, it is known as MRD-positive ALL.¹

Because your child has MRD-positive ALL, the goal of BLINCYTO® treatment is for your child to become MRD-negative, which means that he or she does not have any detectable traces of cancer left.¹

WHAT IS BLINCYTO®?

BLINCYTO® is not a chemotherapy drug.² It is a type of immunotherapy that engages your child's own immune system to help fight their cancer.²

BLINCYTO® works along with the immune system to help white blood cells find, attack and destroy any cancer cells that remain after chemotherapy.²

STARTING BLINCYTO® THERAPY

DESIGNING YOUR CHILD'S TREATMENT PLAN

Before your child starts BLINCYTO®, your healthcare team will design a treatment plan specifically for your child.

MAKE SURE TO TALK TO YOUR DOCTOR:³

- If your child has any allergies to any other medicines, foods, preservatives or dyes
- If your child has 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 your child has an active infection
- If your child has ever had an infusion reaction after previously using BLINCYTO®
- If your child is taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop
- If you think your child may need any vaccinations in the near future, including those needed to travel to other countries
 - This is because some vaccines must not be given within two weeks before, at the same time as, or in the months after your child receives treatment with BLINCYTO®. Your child's doctor will check if he or she should have the vaccination.

HOW IS BLINCYTO® GIVEN?³

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

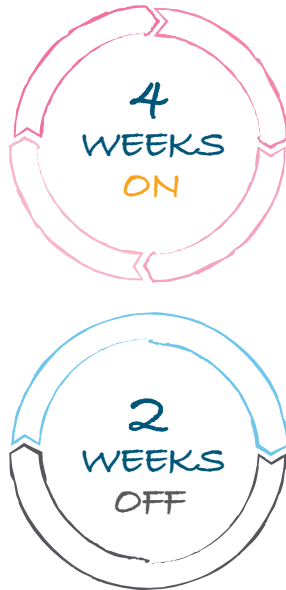
Your child's doctor will determine how often their BLINCYTO® infusion bag or cassette will be changed – this may range from every day to every 4 days.

The infusion rate may be faster or slower depending on how often the bag or cassette is changed.

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 child's response. Your doctor may then decide to give your child another one to three additional cycles of BLINCYTO®.



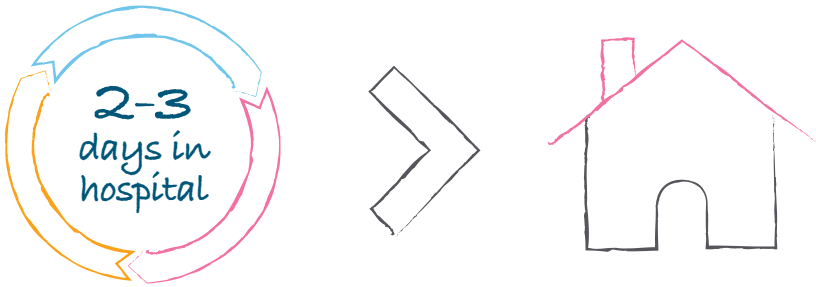
After the 2-week break, your doctor will decide whether your child will be given additional treatment cycles of BLINCYTO®.

WHERE WILL YOUR CHILD BE TREATED?³

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

Your child's doctor will decide what is best for them. They may be asked to stay in hospital for approximately:

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



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

Depending on your child's treatment plan, their doctor may allow them to continue treatment with BLINCYTO[®] at:



MEDICINES GIVEN BEFORE EACH TREATMENT CYCLE³

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

INFUSION PUMP AND INTRAVENOUS TUBING³

Your child will have the pump connected to them 24 hours a day for 28 days. Their healthcare team will advise you on how your child can manage their daily activities around the 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 let your child lie on the tubing.
- ✗ Do not change the pump settings on purpose.
- ✗ Do not let your child pull the tubing or unplug the pump at any time.
- ✓ Contact your child's 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 their vein dry at all times.
- ✓ Contact your child's healthcare team if you have any concerns regarding how their pump is working.

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

THINGS YOU MUST DO DURING TREATMENT³

- ✓ Keep the area around the catheter clean if your child has a catheter for infusion.

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

- ✓ If there is a problem with your child's infusion pump or their pump alarm sounds, contact your child's 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.

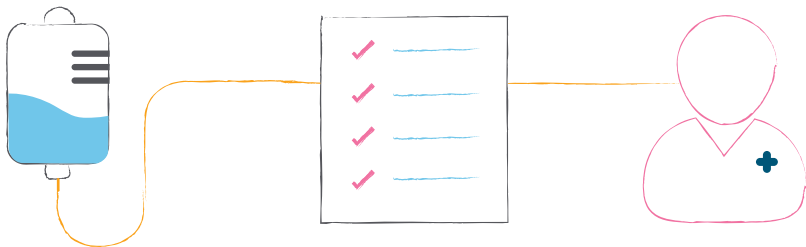
- ✓ Contact your healthcare team immediately:
 - If there is a problem with the pump or if the pump alarm sounds
 - If you think your child may have been given more BLINCYTO[®] than they should have
 - If the infusion pump stops unexpectedly. Do not try to restart the pump

HOW SHOULD BLINCYTO[®] BE STORED?³

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

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

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



POSSIBLE SIDE EFFECTS OF BLINCYTO®³

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. Your child may not experience any of them.

Tell your child's healthcare team or pharmacist if you notice any of the following in your child:

- 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
- Flushing

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

TELL YOUR CHILD'S DOCTOR IMMEDIATELY IF ANY OF THE FOLLOWING HAPPEN IN YOUR CHILD:

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

IMPORTANT THINGS TO REMEMBER WHILE YOUR CHILD IS TAKING BLINCYTO®

Tell your child's doctor, nurse or pharmacist that they are receiving BLINCYTO® before they start any new medicine.

Tell any other doctors who treat your child that they are receiving BLINCYTO®.

Tell your child's doctor, nurse or pharmacist immediately if they 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 child's temperature as they may have a fever – these may be symptoms of an infection.
- **A reaction at any time during their 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 child's dose of BLINCYTO® may need to be adjusted.

Your child's doctor or nurse will monitor them for signs and symptoms of these reactions.

Your child 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. As a result, your child's doctor or nurse will take regular blood tests to monitor their blood counts during treatment with BLINCYTO®.

QUESTIONS TO ASK YOUR CHILD'S DOCTOR ABOUT BLINCYTO®

Here are some common questions that may come up during your child's treatment with BLINCYTO®. Be sure to discuss these questions, or any others that you may have, with your child's doctor.

STARTING TREATMENT:

- What other medications might be prescribed for my child?
- What kind of side effects may occur with BLINCYTO®?
- Is there anything else I need to know to give my child the best chance for a successful treatment?

SUPPORT:

- Are there patient support groups or programs that can help our family?

IF LEAVING THE HOSPITAL:

- How can I best prepare for my child's BLINCYTO® treatment after leaving the hospital?
- How often will my child's BLINCYTO® infusion bag need to be changed?
- Who should I contact if the infusion pump starts beeping, or if there are other problems with the infusion setup?
- How might treatment with BLINCYTO® affect my child's day-to-day activities?
- How should I manage my child's daily activities, such as when he or she is playing with friends or at school?
- How soon should I call my child's doctor if I notice any possible side effects?
- What is the best way to ensure that my child is eating enough throughout the day?
- How will I know when it's time for my child to go back to school?

RETURNING HOME AND GOING BACK TO SCHOOL

You may feel anxious about leaving the hospital setting, but it's important to know that your child's healthcare team is still accessible should any questions or problems arise.

YOU MIGHT CONSIDER:

- Teaching your child about healthy lifestyle habits and how to manage any physical or emotional symptoms they experience.
- Monitoring your child during extended periods of activity and encourage them to take rest breaks throughout the day.
- Preparing multiple, smaller meals or snacks throughout the day for your child. It is important for your child to eat a healthy, balanced diet.

Ask your child's healthcare team for advice on how to best manage the transition from home to school.

SOME TIPS ON EASING THE TRANSITION BACK TO SCHOOL:

- Ask your child's doctor when it may be appropriate for your child to return to school.
- Meet with the teacher and the principal to set expectations for school attendance and classroom participation.
- Provide the school principal with a copy of your child's treatment schedule.
- Discuss and consider alternatives to full days of school.
- Explain your child's diagnosis and treatment to the school nurse and your child's teacher. Discuss side effects and other medical issues to look out for.
- Provide your emergency contact information as well as an emergency medical contact.
- Select a backpack that your child can use to carry their BLINCYTO® infusion pump. Encourage them to decorate it.
- Invite a few classmates to visit your child before returning to school so that your child can catch up on news.
- Identify a 'buddy' to greet your child on their first day back to school.
- Set expectations about the limits of physical activity that your child might be able to handle.
- Follow up with your child's teacher and school nurse to discuss classroom performance and how your child is coping.

EXPLAINING BLINCYTO® TO YOUNG CHILDREN

Your child might experience side effects when being treated with BLINCYTO®. Here are some examples of how you can talk to your child about side effects:

- There are two different parts to your BLINCYTO® treatment. During the first part, you may be treated in the hospital. During the second part, you may be treated at home.
- BLINCYTO® is a medicine that may help your disease go away. But like many types of medicines, being treated with BLINCYTO® might make you feel sick, too.

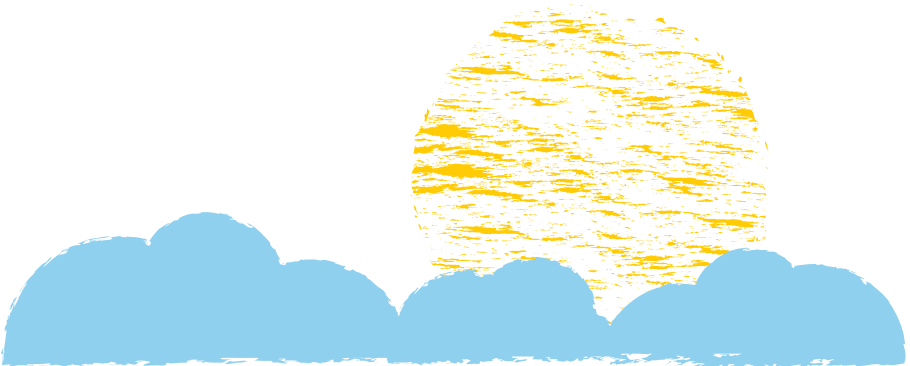
WHEN YOU ARE TAKING BLINCYTO®, YOU MIGHT GET:

- Hot
- A sore head
- Swelling of hands, ankles, or feet
- Feel sick
- A sore tummy
- Changes in your blood

These aren't all of the possible side effects of BLINCYTO®.

If you feel sick, or feel something that bothers you or doesn't go away, tell your parents, teacher or doctor right away.

See the **HOW BLINCYTO® WORKS** tab for a cartoon to help you explain this to your child.



ADMINISTRATION^{2,3}

Your child may be able to receive BLINCYTO® at home or at an outpatient clinic. Here is some information on how you can talk to your child about how BLINCYTO® will be given to him or her:

BLINCYTO® is a medicine that enters your body through your blood.

This is called an infusion. Your infusion bag contains the medicine that is delivered into your blood using an infusion pump. Your pump may beep to let you know when it's running low or if something is wrong. Let your parents or teacher know if you hear your pump beep, or if you think it might need fixing.

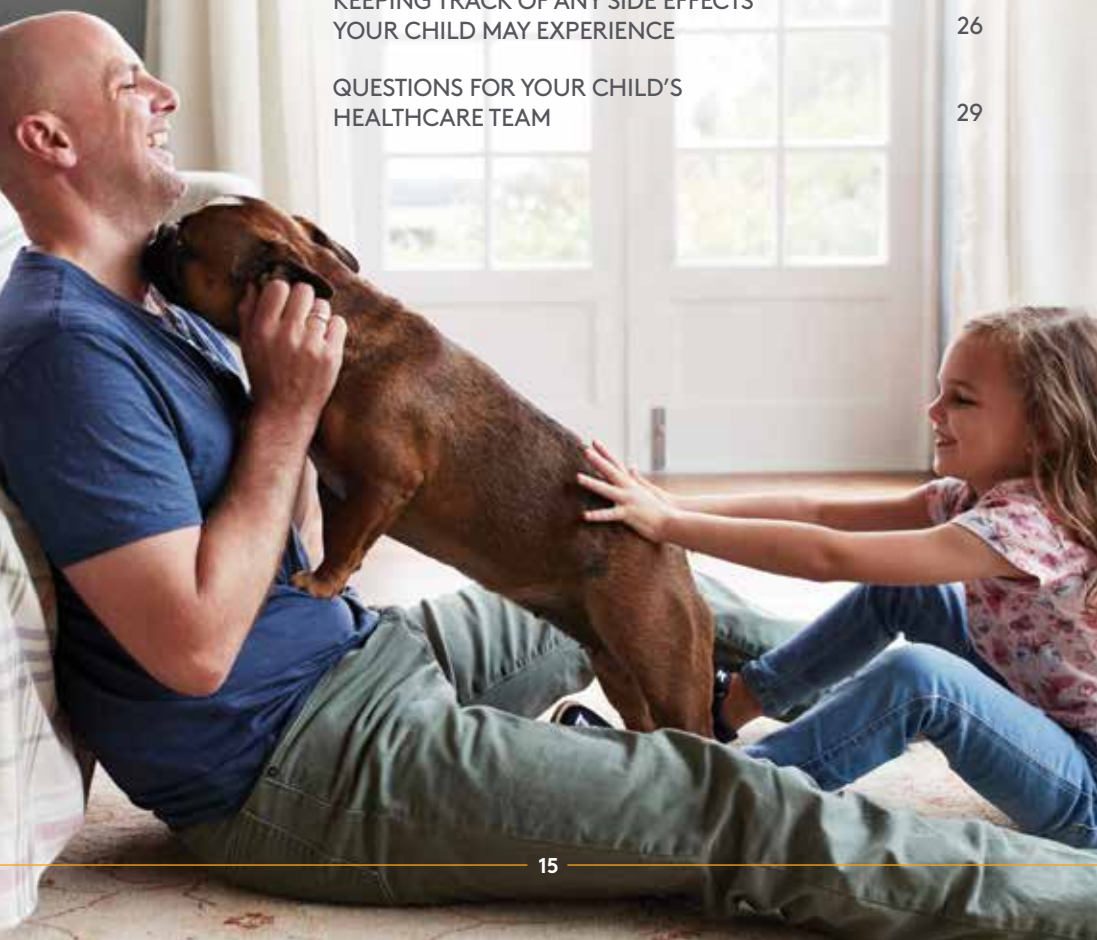
Your BLINCYTO® infusion bag can be stored in a backpack that you can carry around. You can decorate your backpack with fun colours and stickers.

TREATMENT DIARY

TABLE OF CONTENTS

YOUR CHILD'S TREATMENT RESOURCES

YOUR CHILD'S HEALTHCARE TEAM	17
YOUR CHILD'S BACKGROUND HEALTH INFORMATION	18
YOUR CHILD'S TREATMENT WITH BLINCYTO®	19
YOUR CHILD'S MEDICAL APPOINTMENTS	22
KEEPING TRACK OF ANY SIDE EFFECTS YOUR CHILD MAY EXPERIENCE	26
QUESTIONS FOR YOUR CHILD'S HEALTHCARE TEAM	29



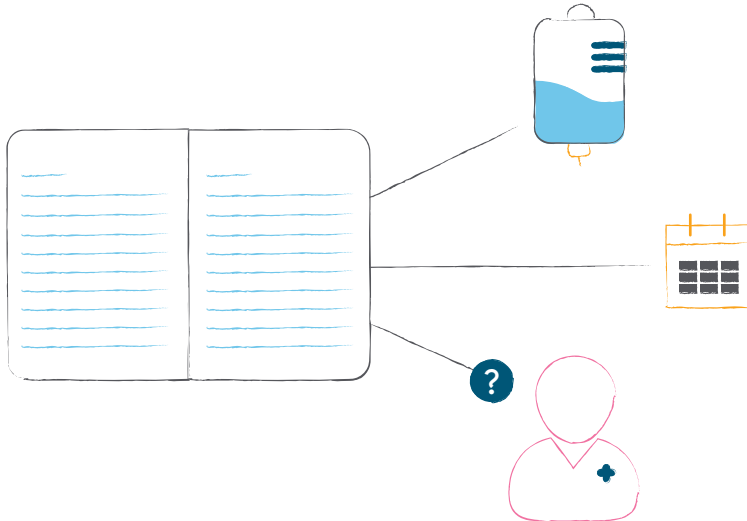
YOUR DIARY TO TRACK YOUR CHILD'S TREATMENT

Having a child diagnosed with a condition like MRD-positive ALL can feel overwhelming at times.

Many parents have found it helpful to use a diary to help track information such as their child's treatment schedule and any issues related to their condition and its treatment.

As your child begins their treatment with BLINCYTO®, you can use this diary to track their progress and to write down any side effects they may experience or questions you may have for your child's healthcare team. The diary is also a good place to record details of other medicines your child is 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 child's medical appointments so you can share this information with all members of your child's healthcare team. The more information you can share with your child's healthcare team, the better equipped you should be to discuss your child's condition and its treatment with BLINCYTO®.



YOUR CHILD'S HEALTHCARE TEAM

Record the contact details of your child's healthcare team here. This might include your child's haematologist or oncologist, 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:

YOUR CHILD'S BACKGROUND HEALTH INFORMATION

Does your child have any other health problems that you are aware of?

Is your child currently taking any medication for other health problems?

Does your child have any allergies?

YOUR CHILD'S TREATMENT WITH BLINCYTO®

This tool will help you stay organised on your child's treatment journey. Use this calendar to keep track of scheduled appointments and bag changes.

The next time you meet with your child's 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 your child starts their BLINCYTO® treatment.
3. Then count out when your child's bag changes will occur: 1 day, 2 days, 3 days, or 4 days. For example, if your child gets a 2-day bag on Tuesday, your child's 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

YOUR CHILD'S 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: _____

YOUR CHILD'S MEDICAL APPOINTMENTS

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

Date and time: _____

Location: _____

Appointment with: _____

Purpose: _____

Notes: _____

Date and time: _____

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YOUR CHILD'S MEDICAL APPOINTMENTS

Date and time: _____

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Appointment with: _____

Purpose: _____

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Purpose: _____

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YOUR CHILD'S 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: _____

KEEPING TRACK OF ANY SIDE EFFECTS YOUR CHILD MAY EXPERIENCE

Use these pages to keep track of any side effects your child may experience. Remember to talk to your child's healthcare team about these at your next appointment.

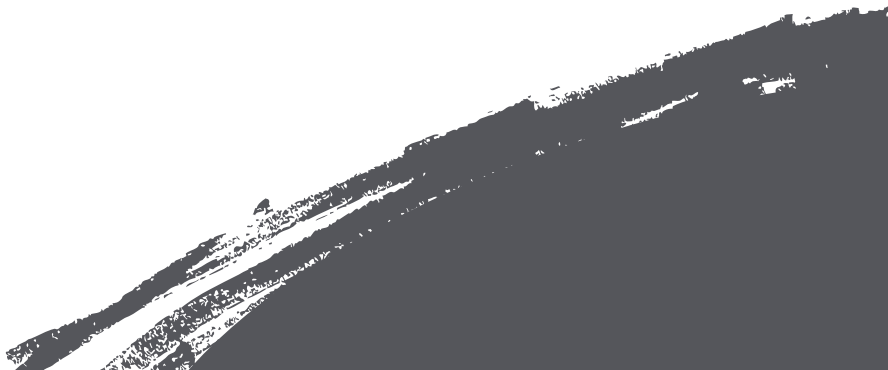
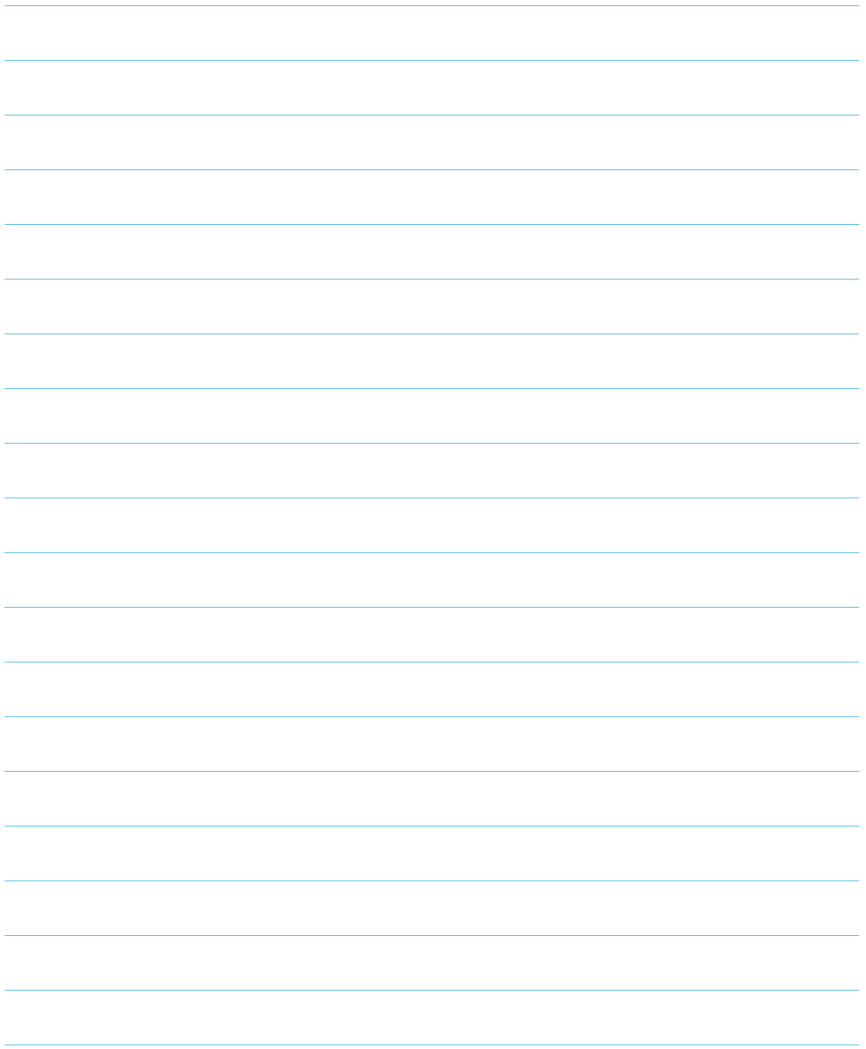
Date and time of day	Suspected side effect

QUESTIONS FOR YOUR CHILD'S HEALTHCARE TEAM

Use this page to write down any questions you have for your child's healthcare team. This will help remind you to ask them at your child's next appointment.

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EXPLAINING BLINCYTO® TO YOUNG CHILDREN

To prepare your child for treatment, it may be a good idea to help them understand how BLINCYTO® works.^{2,3}

The blood in our bodies is made up of lots of little pieces called 'cells' that do different things. Normal cells help you stay healthy, but other cells can change and make you sick.



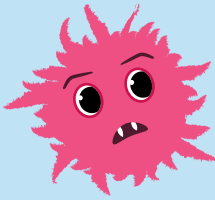
Normal cell



Normal cell

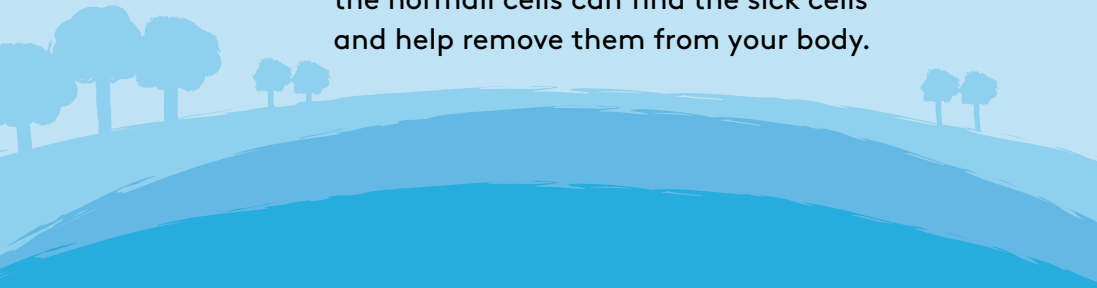


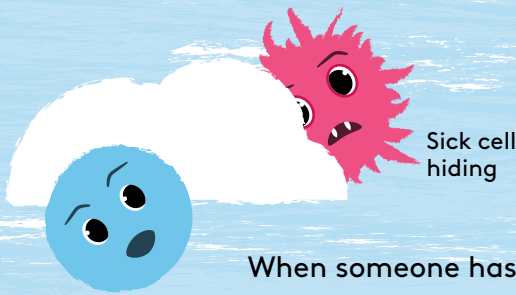
Normal cell finds sick cell



Sick cell

When cells change and make you sick, the normal cells can find the sick cells and help remove them from your body.





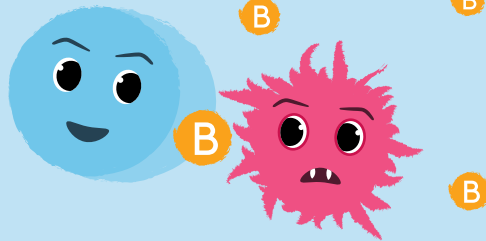
When someone has ALL, the cells that might make you sick can hide from the cells that can help you feel better.



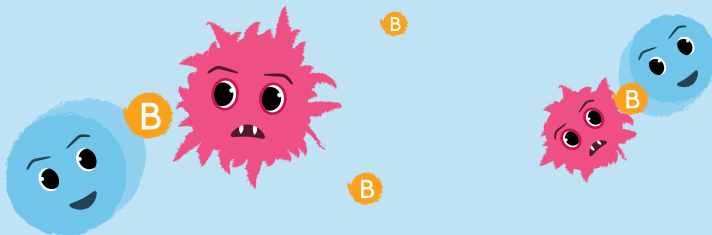
The treatment you have already been given helped remove most of these sick cells from your body. But there are still a few left.



BLINCYTO®



BLINCYTO® can help the cells that make you feel better by finding these hiding cells. Once those sick cells are found, your body can then begin to remove them.



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

Alternatively, you can contact Amgen Australia Medical Information on 1800 803 638 for more information on BLINCYTO[®] or to report any adverse event.

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 December 2019. **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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