

BLINCYTO®

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I receiving Blincyto?

Blincyto contains blinatumomab. It is used to treat adults, adolescents, and children with acute lymphoblastic leukaemia (ALL). For more information, see Section [1. Why am I receiving Blincyto?](#) in the full CMI.

2. What should I know before I am given Blincyto?

Do not use if you have ever had an allergic reaction to Blincyto, 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. There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to you before receiving Blincyto (see the full CMI for more details).

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

3. What if I am taking other medicines?

Some medicines may interfere with Blincyto 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 will Blincyto be given?

Blincyto is given by your doctor or nurse as an infusion.

More instructions can be found in Section [4. How will Blincyto be given?](#) in the full CMI.

5. What should I know while using Blincyto?

Things you should do	<ul style="list-style-type: none">● Keep all medical appointments so that your progress can be checked.
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	<ul style="list-style-type: none"> ● To avoid infection, keep the area around the catheter infusion clean. ● Check with the doctor before having any vaccinations. ● Talk to your doctor if you become pregnant or need to start breastfeeding. ● Remind healthcare providers that you are receiving treatment with Blinicyto.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not adjust the settings on the infusion pump. ● Do not breastfeed during Blinicyto treatment and for 48 hours after your last dose.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Do not drive, engage in hazardous activity, or use any heavy machines or tools during Blinicyto treatment. Blinicyto may cause dizziness, confusion, or seizures (fits).

For more information, see Section [5. What should I know during treatment with Blincyto?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache, tingling skin or numbness, rash, cough, cold like symptoms, shortness of breath, pale skin, bleeding or bruising more easily, trouble sleeping, back/bone pain, pain in hands or feet, swollen joints, hands, ankles, feet, abdomen or glands, nose bleeds, nausea, diarrhoea, vomiting, flushing, dizziness, tremor (shaking), tiredness, weight gain.

Serious side effects include fever (temperature of 38°C or above) and signs of infection, infusion-related reaction, allergic reaction, neurologic problems, inflammatory conditions, metabolic disorders, pancreas inflammation and decreased white blood cells.

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.

WARNING: In some patients, Blincyto may cause serious side effects that can be severe, life-threatening, or lead to death.

Call your doctor and get medical attention immediately if you experience any of the symptoms listed below.

- **Fever, tiredness or weakness, dizziness, low blood pressure, headache, nausea, vomiting, chills, face swelling, wheezing or trouble breathing, skin rash (symptoms of Cytokine Release Syndrome and infusion reactions).**
- **Seizures, difficulty in speaking or slurred speech, loss of consciousness, trouble sleeping, confusion, disorientation, loss of balance, headache, difficulty with facial movements/hearing/vision/swallowing (symptoms of neurologic problems including immune effector cell-associated neurotoxicity syndrome (ICANS)).**

BLINCYTO® (blin-SY-toh)

Active ingredient(s): *Blinatumomab (BLIN-a-TOOM-oh-mab)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Blincyto. **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 Blincyto.

Where to find information in this leaflet:

- [1. Why am I receiving Blincyto?](#)
- [2. What should I know before I am given Blincyto?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will Blincyto be given?](#)
- [5. What should I know during treatment with Blincyto?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I receiving Blincyto?

Blincyto contains the active ingredient blinatumomab. Blincyto is an antineoplastic agent which targets cancer cells. This medicine works by enabling your immune system to attack and destroy abnormal white blood cancer cells.

Blincyto is used to treat children, adolescents, and adults with acute lymphoblastic leukaemia (ALL). ALL is a cancer of the blood in which a particular type of white blood cell is growing out of control.

2. What should I know before I am given Blincyto?

Warnings

Do not use Blincyto if you have an allergy to:

- blinatumomab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- any medicine that is made using Chinese Hamster Ovary cells.

Tell your doctor if you:

- have ever had neurological problems such as seizures, memory loss, confusion, disorientation, loss of balance, or difficulty in speaking
- have an active infection
- have ever had an infusion reaction after previously using Blincyto
- are pregnant or breastfeeding
- take any medicines for any other condition.

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

The effects of Blincyto in pregnant women are not known. Tell your doctor or nurse if you think you are pregnant, or plan become pregnant. Your doctor will help you weigh the benefit against the risk of taking Blincyto during pregnancy.

If you can become pregnant, use birth control (contraception) during treatment and for 48 hours after your last Blincyto treatment. Talk to your doctor or nurse about suitable methods of contraception.

Your doctor may need to talk to you about precautions in using vaccinations for your baby.

Breastfeeding

Tell your doctor or nurse if you are breastfeeding or planning to breastfeed.

It is not known if the active ingredient of Blincyto passes into breast milk. Do not breastfeed during Blincyto treatment and for at least 48 hours after the last treatment.

3. What if I am taking other medicines?

Tell your doctor or nurse if you think you may need any vaccinations. This includes any vaccines needed to travel to other countries. Some vaccines must not be given 2 weeks before you start treatment with Blincyto,

during your treatment, and for some months after you received your last cycle of Blincyto.

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.

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

4. How will Blincyto be given?

Blincyto will always be given to you by a doctor or nurse. Before each Blincyto treatment, you will be given other medicines (pre-medication) to help reduce any adverse reactions. These medicines may include corticosteroids.

Your doctor or nurse will give you Blincyto as a slow, continuous infusion into a vein (intravenous).

You will be required to stay in a hospital or clinic for up to 9 days of the first cycle and the first 2 days of the second cycle of Blincyto. The exact duration of your hospital stay will depend on the stage of your disease (eg, whether you are undergoing treatment of minimal residual disease or newly diagnosed consolidation treatment or treatment for relapsed or refractory ALL). The staff will monitor you for signs and symptoms of any serious reactions in hospital. Follow their instructions when receiving Blincyto.

Detailed instructions on how to prepare Blincyto are included in the pack leaflet. Your doctor, nurse, or pharmacist will prepare the IV bags or cassettes containing Blincyto solution for infusion.

How much Blincyto will I be given

Your doctor will calculate how much Blincyto you will be given. The dose given is based on a combination of your weight, height, and your condition.

Your doctor will determine when your Blincyto infusion bag or cassette will be changed. This could be once daily or up to once every 4 days. The infusion rate may be faster or slower depending on how often the bag or cassette is changed. You may not be able to tell the difference between the different infusion rates.

For patients with relapsed or refractory ALL, the dose of Blincyto should be increased for weeks 2, 3, and 4 of your first cycle depending on how you respond to treatment with Blincyto. You may not be able to tell the difference between the dose delivered during the first week of your first cycle and the increased dose delivered for the remainder of the first cycle and for the subsequent cycles.

For patients with MRD-positive ALL, the dose should remain the same.

For patients undergoing treatment with Blincyto in the consolidation phase, the dose should remain the same.

When Blincyto is given

Blincyto is given in repeating "cycles" lasting 6 weeks.

- **First 4 weeks** - Blincyto is given as a continuous slow infusion into a vein (using an infusion pump).
- **Next 2 weeks** – Treatment break during which you will not be given the infusion.

The number of treatment cycles that will be given will depend on how well you respond to Blincyto. Treatment may be interrupted depending on how well you tolerate Blincyto. Your doctor will discuss how long your treatment will last.

How to manage the infusion pump

- Your doctor or nurse will advise you on how to manage your daily activities around your infusion pump. Normal everyday activities will not affect the infusion pump and intravenous tubing.
- Contact your doctor or nurse if you have questions about your daily activities and pump function.

See additional information under Section [5. What should I know while using Blincyto?](#)

If you are given too much Blincyto

As Blincyto is given to you under the supervision of your doctor, it is unlikely that you will receive too much. However, if you think you have been given too much Blincyto or experience severe side effects after

being given this medicine, tell your doctor or nurse immediately. You may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

5. What should I know during treatment with Blincyto?

Things you should do

- **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 doctor or nurse will show you how to care for your catheter site. Keep the area dry when showering or bathing.

Contact your doctor or nurse immediately if you have pain, discomfort, redness or swelling around the site.
- Check your temperature if you feel warm, have chills or shivering. You may have a fever (temperature of 38°C or higher) and an infection.
- Keep all medical appointments. Your doctor will do tests during treatment to check on your progress and for any side effects.
- Tell your doctor if you become pregnant while on this treatment.

If you are pregnant, your doctor may need to talk to you about precautions of receiving vaccinations.

- Tell your doctor or nurse 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.
- Remind any doctor, dentist, or pharmacist you visit that you are using Blincyto.

Call your doctor straight away if:

- there is a problem with the infusion pump or if the pump alarm sounds
- the infusion bag empties before the scheduled bag change
- the infusion pump stops unexpectedly. Do not try to restart the pump
- if you experience seizures, difficulty in speaking or slurred speech, confusion and disorientation, or loss of balance. These may be symptoms of neurological problems associated with a condition called immune effector cell-associated neurotoxicity syndrome (ICANS).
- if you develop chills or shivering, or feel warm; you should take your temperature as you may have a fever – these may be symptoms of an infection

- if you develop a reaction to Blincyto at any time during your infusion, which may include dizziness, face swelling, difficulty breathing, wheezing, or rash
- if you have severe and persistent stomach pain, with or without nausea and vomiting, as these may be symptoms of a serious and potentially fatal condition known as pancreatitis (inflammation of the pancreas).

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

People with Down syndrome may have a higher risk of seizures with Blincyto treatment and may be given anti-seizure medicine before starting Blincyto treatment.

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

Things you should not do

- Do not adjust the settings on the infusion pump.
- Do not stop or try to restart the infusion pump.

Driving or using machines

Do not drive, engage in hazardous activity, or use any heavy machines or tools while you are being given Blincyto. Blincyto may cause dizziness, fits (seizures), and confusion in some people.

Looking after your medicine

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

Getting rid of any unwanted medicine

Do not use this medicine after the expiry date.

Your doctor, nurse or pharmacist will dispose of any unwanted medicine in accordance with local requirements.

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
Blood <ul style="list-style-type: none">• bleeding or bruising more easily than normal Skin	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● rash ● feeling of pins and needles, tingling of skin, or numbness ● decreased feeling or sensitivity ● flushing (feeling warm and rapid reddening of your neck, upper chest, or face) ● pale skin <p>Eyes, ears and mouth</p> <ul style="list-style-type: none"> ● sore throat ● mouth ulcers <p>Heart</p> <ul style="list-style-type: none"> ● fast heartbeat <p>Lungs and upper airway</p> <ul style="list-style-type: none"> ● wet or dry cough ● shortness of breath when exercising ● runny nose ● nose bleeds <p>Gut and digestion</p> <ul style="list-style-type: none"> ● nausea ● vomiting ● diarrhoea 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● swelling in the abdomen <p>Brain and nerves</p> <ul style="list-style-type: none"> ● headache ● dizziness and light headedness ● tremor <p>Muscle and skeleton</p> <ul style="list-style-type: none"> ● back, chest, or bone pain ● pain in hands or feet ● painful/swollen joints <p>General</p> <ul style="list-style-type: none"> ● tiredness ● weight increase ● general swelling of the face, lips, mouth, tongue, hands, ankles or feet ● swollen glands in the neck, armpit or groin 	

Serious side effects

Serious side effects	What to do
<p>Signs of infection:</p> <ul style="list-style-type: none">• chills or shivering, or feel warm; you should take your temperature as you may have a fever <p>Signs of an infusion-related reaction:</p> <ul style="list-style-type: none">• dizziness• swelling• pain where the infusion needle is inserted• rash, blisters, itching• nausea, vomiting, constipation, diarrhoea (usually occurring within the first 48 hours) <p>Signs of an allergic reaction:</p> <ul style="list-style-type: none">• shortness of breath, wheezing or difficulty breathing• swelling of the face, lips, mouth, tongue, throat or other parts of the body	<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"> ● rash, itching or hives on the skin <p>Signs of neurologic events:</p> <ul style="list-style-type: none"> ● headache ● shaking (tremor) ● convulsions or fits (seizures) ● confusion and disorientation ● drowsiness ● tingling or numbness ● reduced sensitivity to touch ● difficulty in speaking, communicating, thinking or processing thoughts, or remembering things ● loss of balance, dizziness ● trouble sleeping (insomnia) ● visual disturbances ● difficulty with facial movements, trouble swallowing ● difficulty hearing 	

Serious side effects	What to do
<p>These may be symptoms of neurological problems associated with a condition called immune effector cell-associated neurotoxicity syndrome (ICANS).</p> <p>Signs of an inflammatory condition:</p> <ul style="list-style-type: none"> • fever, chills • swelling • dizziness and light headedness • fluid in the lungs, which may become severe 	

Serious side effects	What to do
<p>Signs of metabolic disorders:</p> <ul style="list-style-type: none"> • high fever, chills • difficulty breathing • nausea, loss of appetite, vomiting, diarrhoea • skin rash • increased or irregular heartbeat 	<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"> ● swelling and buildup of fluids in the legs or feet ● headache, confusion, disorientation, dizziness, fits (seizures), shaking (tremor), difficulty with facial movements, trouble speaking or slurred speech, loss of balance ● joint or muscle aches <p>Signs of pancreas inflammation:</p> <ul style="list-style-type: none"> ● severe and persistent stomach pain, with or without nausea and vomiting <p>Signs of decreased white blood cells:</p> <ul style="list-style-type: none"> ● fever and other signs of infection, such as shivers, chills, shakes ● sore throat ● difficulty or burning when passing urine ● feeling unwell 	

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

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

Some side effects can only be found when your doctor does tests to check your progress. These may pick up changes in:

- the size of your lymph nodes, liver, or spleen
- red cells, white cells, platelets, or antibodies in your blood
- your blood pressure or heart rate
- levels of some salts (electrolytes) or uric acid in your blood
- liver enzymes or other liver test results.

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 Blincyto contains

Active ingredient (main ingredient)	blinatumomab 38.5 micrograms
Other ingredients (inactive ingredients)	citric acid monohydrate (E330) trehalose dihydrate lysine hydrochloride polysorbate 80 (E433) sodium hydroxide (E524) water for injections Blincyto contains less than 1 mmol (23 milligrams) sodium per dose.

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

What Blincyto looks like

Each pack of Blincyto contains:

- 1 single-use Blincyto clear glass vial containing a sterile, preservative free, white to off-white lyophilised powder
- 1 single-use IV Solution Stabiliser vial containing sterile, preservative-free, colourless-to slightly yellow, clear solution.

(AUST R 232805)

Who distributes Blincyto

Amgen Australia Pty Ltd

Level 11, 10 Carrington St

Sydney NSW 2000

Ph: 1800 803 638

www.amgenmedinfo.com.au

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