

WHAT IS BLINCYTO® (blinatumomab)?

BLINCYTO® is a prescription medicine used to treat adults and children 1 month and older with:

- B-cell precursor acute lymphoblastic leukemia (ALL) in remission when only a small number of cancer cells remain in the body (minimal residual disease)
- B-cell precursor ALL that has come back or did not respond to previous treatments
- Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of chemotherapy treatment with multiple phases

ALL is a cancer of the blood in which a particular kind of white blood cell is growing out of control. It is not known if BLINCYTO® is safe and effective in children less than 1 month of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about BLINCYTO®?

- Call your health care provider or get emergency medical help right away if you get any of the symptoms listed below:
 - BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death, including:
 - Cytokine Release Syndrome (CRS) and infusion reactions. Symptoms of CRS and infusion reactions may include: fever, tiredness or weakness, dizziness, headache, low blood pressure, nausea, vomiting, chills, face swelling, wheezing or trouble breathing, and skin rash.



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What is ALL?

Acute lymphoblastic leukemia (ALL) is a type of cancer of the blood and bone marrow that affects white blood cells. These white blood cells are important to your immune system because they play a role in helping your body fight infection and disease. But when you have ALL, the bone marrow makes too many of these white blood cells and they do not work properly.^{2,3}

Remission means that your body is free of signs and symptoms of cancer. **Remission is a great achievement,** but it does not mean the cancer has been cured.^{2,4}

Along with the news that your ALL is in remission, your doctor may have talked to you about testing for remaining traces of cancer. Or you may have already been tested but wonder what it's all about.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about BLINCYTO®?

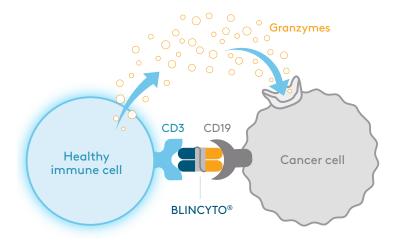
- Call your health care provider or get emergency medical help right away if you get any of the symptoms listed below:
 - BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death, including:
 - **Neurologic problems.** Symptoms of neurologic problems may include: seizures, difficulty in speaking or slurred speech, loss of consciousness, trouble sleeping, confusion and disorientation, loss of balance, headache, difficulty with facial movements, hearing, vision, or swallowing, and tremors. People with Down Syndrome may have a higher risk of seizures with BLINCYTO® treatment.
 - Your health care provider will check for these problems during treatment with BLINCYTO[®]. Your health care provider may temporarily or completely stop your treatment with BLINCYTO[®] if you have severe side effects.



BLINCYTO[®] uses your body's own immune system to fight cancer¹

BLINCYTO® is an **immunotherapy**. It is different from chemotherapy because it engages your immune system to find and kill cancer cells.^{1,2}

- 1. Finds: Cancer cells can hide from healthy immune cells. BLINCYTO® helps the healthy immune cells find the cancer cells and bring them together.^{1,4}
- Activates: When the healthy cells and cancer cells are connected, BLINCYTO® activates the healthy immune cells to release specialized proteins called granzymes.⁵
- **3. Kills:** The granzymes then attack and kill the cancer cells.⁵



Your treatment with BLINCYTO®

The good news is that BLINCYTO® has been proven to help a wide range of people with different types of ALL live longer. So, whether you've had initial therapy and are now in the next phase of treatment, or if your cancer has returned (relapsed) or hasn't responded to treatment (refractory), BLINCYTO® may be able to help.¹

To see how BLINCYTO® can help¹,4

- People with Philadelphia chromosome-negative (Ph(-)) B-cell precursor (BCP) ALL who've had initial therapy and are now in the next phase of treatment, go to page 5
- People whose BCP-ALL is in remission, but still have detectable traces of cancer (minimal residual disease or MRD) after chemotherapy, go to page 6
- People with BCP-ALL whose cancer has returned or did not respond to treatment, go to page 7

IMPORTANT SAFFTY INFORMATION

Who should not receive BLINCYTO®?

• Do not receive BLINCYTO® if you are allergic to blinatumomab or to any of the ingredients of BLINCYTO®.



In Ph(-) BCP-ALL

BLINCYTO® used after initial treatment

BLINCYTO® was studied in 224 adults aged 30-70 years with newly diagnosed Ph(-) BCP-ALL. The goal of the study was to see whether people lived longer when BLINCYTO® was used with chemotherapy vs chemotherapy alone, after initial treatment. This period of treatment is known as the consolidation phase.1

Of the 224 people, half were given both BLINCYTO® and chemotherapy. The other half were given only chemotherapy.¹

In Ph(-) BCP-ALL

Treatment with BLINCYTO® helped people live longer¹



At 3 years, 85% of the 112 people who received BLINCYTO® with chemotherapy were still alive vs 69% of the 112 who received chemotherapy alone. 1,*



(out of 112 people)

63% Chemotherapy alone

(out of 112 people)









In this study, most people were given 4 cycles of BLINCYTO[®].1 Your doctor will decide how long you will stay on treatment.

*This analysis looked at survival for 3.6 years, and the percentage of people alive at 3 years was estimated.1 †This analysis looked at survival for 4.5 years, and the percentage of people alive at 5 years was estimated.¹¹.6

IMPORTANT SAFETY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- o have a history of neurological problems, such as seizures, confusion, trouble speaking or loss of balance
- have Down Syndrome





What is MRD? Why should I be tested?

Cancer can often hide from treatments, making it hard to get rid of all cancer cells. Even after achieving remission with chemotherapy, a relatively small number of cancer cells can remain in your body. This is called minimal residual disease, or MRD. **MRD-negative** means there are no detectable traces of cancer left.⁴

MRD can cause a relapse, which is the return of a disease or signs and symptoms of a disease after a period of improvement.^{2,4}



Ask your doctor about getting tested

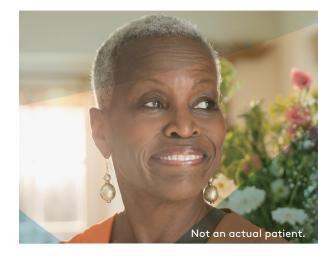
In another trial, BLINCYTO® was studied in 86 adults with BCP-ALL who tested **MRD-positive** after chemotherapy. The goal was to become MRD-negative so there were no detectable traces of cancer left.¹

BLINCYTO® helped people become MRD-negative1,*



8 out of 10 (81%) had no detectable cancer after 4 weeks^{1,†,‡}

More than half of the people treated with BLINCYTO® were able to get to transplant.^{1,§}



*As measured by a test that can detect 1 cancer cell out of 10,000 cells in the bone marrow. (More sensitive testing methods may be able to detect lower levels of cancer cells.)^{1,4}

†Adults studied had at least 3 rounds of chemotherapy prior to treatment with BLINCYTO®. They were in complete remission either for the first or second time. Remission is a response to treatment where signs of cancer have disappeared but it does not always mean the cancer is cured.^{1,2} †One cycle of treatment with BLINCYTO® consists of four weeks of treatment followed by two weeks without treatment.¹ §59 out of 86 patients treated with BLINCYTO® in the study proceeded to a transplant.¹

IMPORTANT SAFETY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- have an infection
- have ever had an infusion reaction after receiving BLINCYTO® or other medications
- have a history of radiation treatment to the brain, or chemotherapy treatment
- are scheduled to receive a vaccine. You should not receive a "live vaccine" within 2 weeks before you start treatment with BLINCYTO®, during treatment, and until your immune system recovers after you receive your last cycle of BLINCYTO®. If you are not sure about the type of vaccine, ask your health care provider.





BLINCYTO® helped people whose cancer returned or didn't respond to treatment¹

BLINCYTO® was studied in people with Ph(-) BCP-ALL, whose cancer had returned **(relapsed)** or didn't respond to treatment **(refractory)**. Among those people, 271 were treated with BLINCYTO® and 134 were given chemotherapy.¹

People on BLINCYTO® lived nearly twice as long^{1,*}

7.7 months (median overall survival*) with BLINCYTO® vs 4.0 months with chemotherapy.1

What's more, when treated after first relapse, people on BLINCYTO® had a median survival of 11.1 months vs those on chemotherapy, who had a median survival of 5.5 months.8

For people who relapsed or did not respond to treatment, once on BLINCYTO®, they lived longer than those on chemotherapy.^{1,8}

*Median overall survival is defined as the length of time from the start of treatment to when half of the patients in a treatment group are still alive.²

IMPORTANT SAFETY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- are pregnant or plan to become pregnant. BLINCYTO® may harm your unborn baby. Tell your health care provider if you become pregnant during treatment with BLINCYTO®.
 - If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with BLINCYTO[®].
 - Females who are able to become pregnant should use an effective form of birth control (contraception) during treatment with BLINCYTO®, and for 48 hours after your last dose of BLINCYTO®.



How you'll receive BLINCYTO®

BLINCYTO[®] is given by an **intravenous (IV) infusion** into your vein. Dosing of BLINCYTO® occurs in cycles. One cycle is 4 weeks of infusion followed by 2 weeks without infusion.^{1,2}







Your doctor will decide how long you will need to stay on treatment.

Preparing for and getting treatment^{1,9}

BLINCYTO® treatment starts in the hospital to make sure that it is safe for you and to prevent and manage any side effects that may occur.1

- You'll be given a medicine to help reduce the likelihood of infusion reactions, which are common for medicines like BLINCYTO®9
- You will be monitored and treated for any serious reactions to BLINCYTO® if they happen9

For the first cycle, a hospital stay of 3 to 9 days is recommended.¹ For the second cycle, a hospital stay of 2 days is recommended.¹

The length of your hospital stay will depend on whether you are receiving BLINCYTO® early after initial therapy, to treat MRD, or to treat cancer that has returned or not responded to treatment.¹













IMPORTANT SAFETY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

o are breastfeeding or plan to breastfeed. It is not known if BLINCYTO® passes into your breast milk. You should not breastfeed during treatment with BLINCYTO® and for 48 hours after your last dose.







Customizing your treatment

Afterward, your doctor will decide if you can get the rest of your treatment at home, if that is right for you. Or your doctor may refer you to an outpatient clinic or an infusion center to manage your treatment.⁹

After your hospital stay, you will continue BLINCYTO® with a small, portable IV infusion pump. BLINCYTO® is available in the following infusion bags:¹



The infusion time tells you how long before a bag change is needed. Your doctor will decide which is best for you.

Receiving BLINCYTO® at home9

You got the good news that you can go home. If your doctor decides you're ready to go home with BLINCYTO®:

- Talk to your health care provider about whether your IV bag will be changed at an outpatient center or by your home health care provider
- Call your doctor if you experience any problems or side effects
- Do not change the settings on your pump, even if the alarm sounds. Any setting changes may cause a dose error
- If you are having any problems with your pump, or pump alarm sounds, contact your health care provider immediately
- Keep BLINCYTO® and all medicines out of the reach of other children in the household

IMPORTANT SAFETY INFORMATION

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



Possible side effects⁹

BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death, including:

- Cytokine Release Syndrome (CRS) and infusion reactions: Symptoms of CRS and infusion reactions may include fever, tiredness or weakness, dizziness, headache, low blood pressure, nausea, vomiting, chills, face swelling, wheezing or trouble breathing, and skin rash
- **Neurologic problems:** Symptoms of neurologic problems may include seizures, difficulty in speaking or slurred speech, loss of consciousness, trouble sleeping, confusion and disorientation, loss of balance, headache, difficulty with facial movements, hearing, vision, or swallowing, and tremors. People with Down Syndrome may have a higher risk of seizures with BLINCYTO® treatment

BLINCYTO® may cause serious side effects, including:

- Fever
- Reactions related to infusion of the medicine such as face swelling, low blood pressure, and high blood pressure (infusion-related reactions)
- Headache
- Infection
- Muscle, joint, and bone pain

- Low white blood cell count (neutropenia)
- Nausea
- Low red blood cell count (anemia)
- Low platelet count (thrombocytopenia)
- Diarrhea

BLINCYTO® may cause other serious side effects, including:

- Infections
- Tumor lysis syndrome (TLS)
- Low white blood cell counts (neutropenia)
- Abnormal liver blood test
- Inflammation of the pancreas (pancreatitis)

These are not all the possible side effects of BLINCYTO®.

Call your health care provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



With personalized solutions, Amgen® SupportPlus is here to help





Amgen® Patient Navigator*

A single point of contact for answers about starting your Amgen therapy, navigating your treatment journey, and support to help as you start and stay on therapy as prescribed.



Financial Support

Every patient has unique needs. Amgen SupportPlus is here to provide financial support information and resources, regardless of your current financial situation or the type of insurance you have.*



Amgen SupportPlus

CALL 866-264-2778 Monday to Friday, 9:00 AM to 8:00 PM ET, or visit www.AmgenSupportPlus.com to learn how Amgen can help.

Your care team

Health care providers may be only one part of your support network. Your loved ones will be a huge help on your treatment journey.

Friends and family want to be there for you, but may not know how. Let them know it's okay to ask questions and check in with you. And remember, you can ask for help, too. They are there for you.

In addition to your personal caregivers, there are patient support groups that can provide invaluable support throughout the treatment process, such as The Leukemia & Lymphoma Society at <u>Ils.org</u>.

You may also want to reach out to the American Cancer Society at cancer.org.

Adolescents and young adults may want to check out **stupidcancer.org**.

These third-party resources are for your information only. Amgen does not endorse and is not responsible for the content included in these resources.



^{*}The Amgen Patient Navigator is not part of a patient's treatment team and does not provide medical advice or case management services. The Amgen Patient Navigator does not administer Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

Important safety information

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 - Neurologic problems. Symptoms of neurologic problems may include: seizures, difficulty in speaking or slurred speech, loss of consciousness, trouble sleeping, confusion and disorientation, loss of balance, headache, difficulty with facial movements, hearing, vision, or swallowing, and tremors. People with Down Syndrome may have a higher risk of seizures with BLINCYTO® treatment.
 - Your health care provider will check for these problems during treatment with BLINCYTO®. Your health care provider may temporarily or completely stop your treatment with BLINCYTO® if you have severe side effects.

Who should not receive BLINCYTO®?

• Do not receive BLINCYTO® if you are allergic to blinatumomab or to any of the ingredients of BLINCYTO®.

Before receiving BLINCYTO®, tell your health care provider about all of your medical conditions, including if you or your child:

- have a history of neurological problems, such as seizures, confusion, trouble speaking or loss of balance
- o have Down Syndrome
- have an infection
- have ever had an infusion reaction after receiving BLINCYTO® or other medications
- have a history of radiation treatment to the brain, or chemotherapy treatment
- are scheduled to receive a vaccine. You should not receive a "live vaccine" within 2 weeks before you start treatment with BLINCYTO®, during treatment, and until your immune system recovers after you receive your last cycle of BLINCYTO®. If you are not sure about the type of vaccine, ask your health care provider.
- are pregnant or plan to become pregnant BLINCYTO® may harm your unborn baby. Tell your health care provider if you become pregnant during treatment with BLINCYTO®.
 - If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with BLINCYTO[®].
 - Females who are able to become pregnant should use an effective form of birth control (contraception) during treatment with BLINCYTO®, and for 48 hours after your last dose of BLINCYTO®.
- are breastfeeding or plan to breastfeed. It is not known if BLINCYTO® passes into your breast milk.
 You should not breastfeed during treatment with BLINCYTO® and for 48 hours after your last dose.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What should I avoid while receiving BLINCYTO®?

 Do not drive, operate heavy machinery, or do other dangerous activities while you are receiving BLINCYTO® because BLINCYTO® can cause neurological symptoms such as dizziness, seizures, and confusion.

BLINCYTO® may cause serious side effects, including:

• Infections. BLINCYTO® may cause life-threatening infections that may lead to death. Tell your health care provider right away in case you develop any signs or symptoms of an infection.



Important Safety Information (cont'd)

- Tumor Lysis Syndrome (TLS). TLS is caused by the fast breakdown of cancer cells. TLS can be life-threatening and may lead to death. Tell your health care provider right away if you have any symptoms of TLS during treatment with BLINCYTO®, including: nausea and vomiting, confusion, shortness of breath, irregular heartbeat, dark or cloudy urine, reduced amount of urine, unusual tiredness, muscle cramps.
- Low white blood cell counts (neutropenia). Neutropenia is common with BLINCYTO® treatment and may sometimes be life-threatening. Low white blood cell counts can increase your risk of infection. Your health care provider will do blood tests to check your white blood cell counts during treatment with BLINCYTO®. Tell your health care provider right away if you get a fever.
- Abnormal liver blood test. Your health care provider will do blood tests to check your liver before you start BLINCYTO® and during treatment with BLINCYTO®.
- Inflammation of the pancreas (pancreatitis).

 Pancreatitis may happen in patients treated with

 BLINCYTO® and corticosteroids. It may be severe and
 lead to death. Tell your health care provider right away
 if you have severe stomach-area pain that does not go
 away. The pain may happen with or without nausea
 and vomiting.
- Your health care provider will do blood tests during treatment to check for side effects.

The most common side effects

- The most common side effects of BLINCYTO® include:
 - Fever
 - Reactions related to infusion of the medicine such as face swelling, low blood pressure, and high blood pressure (infusion-related reactions)
 - Headache
 - Infection
 - O Muscle, joint, and bone pain
 - Low white blood cell count (neutropenia)
 - Nausec
 - Low red blood cell count (anemia)
 - Low platelet count (thrombocytopenia)
 - Diarrhea

These are not all the possible side effects of BLINCYTO®. Call your health care provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please read the accompanying Medication Guide before you or your child receives BLINCYTO® and before each BLINCYTO® infusion and discuss it with your doctor.

Please see BLINCYTO® <u>full Prescribing Information</u>, including BOXED WARNINGS and <u>Medication Guide</u>.





Resources for you

Doctor discussion guide: This guide will help you talk to your doctor about BLINCYTO®. It contains a list of FAQs.

Treatment tracker: This calendar helps you keep track of scheduled appointments and bag changes.

Medical information card: Fill out this medical information card. You can keep your important health care contact information in one place here.

Go to **www.blincyto.com** to download these helpful tools.

Glossary 2,4

Acute lymphoblastic leukemia (ALL): A blood cancer in which the bone marrow makes too many lymphoblasts—a certain type of white blood cell.

Chemotherapy: A treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. It is often called "chemo."

Immunotherapy: A type of medicine that uses your body's own immune system to help fight conditions such as cancer.

Infusion: A method of putting fluids, including drugs, into the bloodstream. It is also called "intravenous infusion."

Intravenous (IV): A way of giving a drug through a needle into a vein

Minimal residual disease (MRD): A relatively small number of cancer cells that remain in the body after treatment and that cannot be detected by standard diagnostic techniques.

MRD-positive: A test result that showed small amounts of cancer after you have completed treatment.

MRD-negative: A test result that found no detectable cancer cells after you have completed treatment.

Refractory: A disease or condition that does not respond to treatment.

Relapse: The return of a disease or the signs and symptoms of a disease after a period of improvement.

Remission: A response to treatment where signs and symptoms of cancer have disappeared. This does not always mean the cancer has been cured.





References: 1. BLINCYTO® (blinatumomab) prescribing information, Amgen. 2. National Cancer Institute. NCI Dictionary of Cancer Terms. https://www.cancer.gov/publications/dictionaries/cancer-terms. Accessed January 23, 2025. 3. Children's Hospital of Philadelphia. Acute Lymphoblastic Leukemia (ALL). https://chop.edu/conditions-diseases/acute-lymphoblastic-leukemia-all. Accessed January 23, 2025. 4. Brüggemann M, Gökbuget N, Kneba M. Acute lymphoblastic leukemia: monitoring minimal residual disease as a therapeutic principle. Semin Oncol. 2012;39:47-57. 5. Nagorsen D, Baeuerle PA. Immunomodulatory therapy of cancer with T cell-engaging BiTE antibody blinatumomab. Exp Cell Res. 2011;317:1255-1260. 6. Data on file, Amgen; 2024. 7. Berry DA, Zhou S, Higley H, et al. Association of minimal residual disease with clinical outcome in pediatric and adult acute lymphoblastic leukemia: A meta-analysis. JAMA Oncol. 2017;3:e170580. 8. Dombret H, Topp MS, Schuh AC, et al. Blinatumomab versus chemotherapy in first salvage or in later salvage for B-cell precursor acute lymphoblastic leukemia. Leuk Lymphoma. 2019;60:2214-2222. 9. BLINCYTO® (blinatumomab) medication guide, Amgen.

Please see BLINCYTO® full <u>Prescribing Information</u>, including BOXED WARNINGS and <u>Medication Guide</u>.



