BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

If you've had initial therapy and are now in the next phase of treatment

Treat your B-cell precursor ALL with BLINCYTO®[1]

A guide for children, teenagers, and their caregivers



Not an actual patient.

ALL, acute lymphoblastic leukemia.

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.

Please see additional Important Safety Information, including **BOXED WARNINGS** and Medication Guide, for BLINCYTO® on pages 22–23.

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Talk to Kids

Hello! I'm here to help you talk about ALL and BLINCYTO® to kids.

Look for this special boxed feature as you read through this brochure.

Please see additional Important Safety Information, including **BOXED WARNINGS**, for BLINCYTO® on pages 22–23.

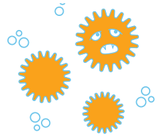
What is ALL?

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]

Talk to Kids

What does it mean to have ALL?

ALL is a type of sickness, called cancer, in the blood. There are different types of cells in the blood. Some are healthy, but other cells can become sick and are called cancer cells. The number of cancer cells can grow and cause problems for the healthy cells.[2,3]



IMPORTANT SAFETY INFORMATION

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

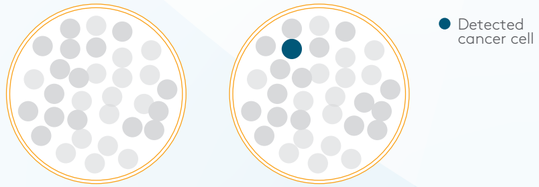
- Call your health care provider or get emergency medical help right away if you get any of the symptoms listed below:
  - **BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death, including:**
    - **Neurologic problems.** Symptoms of neurologic problems may 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 and may be given anti-seizure medicine before starting 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.

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What happens when ALL is treated?

After being treated for ALL, a few different things can happen:

- You may achieve **remission**. This means that signs and symptoms of cancer have decreased or disappeared[2,4]
- Remission is a great achievement, but it does not always mean the cancer is completely gone, as small amounts of disease may still remain[2,4]
- Your doctor may test you for "minimal residual disease", or **MRD**[4]
  - **MRD-negative** means no cancer cells can be detected. However, there could still be some underlying disease.[2,4]
  - **MRD-positive** means there are a relatively small number of cancer cells remaining[2,4]



- Even after you become MRD-negative, your doctor may give you more medicine to help you stay in remission longer[5,6]
- Sometimes leukemia cells or signs and symptoms of cancer can return. This is called a **relapse**[2]
- You may be treated and never reach remission. In this case, the cancer is called **refractory** disease[2]

IMPORTANT SAFETY INFORMATION

Who should not receive BLINCYTO®?

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

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

Talk to Kids

Remission means that the signs and symptoms of your cancer have decreased or disappeared, and you may be feeling better.[2]

Even if you're feeling better after initial chemotherapy, your doctor may still do tests to see if the cancer is gone. More medicine may be needed to help keep you feeling well and prevent the cancer from coming back.[2,4-6]

Relapse means your cancer has come back.[2]

Refractory means your cancer is stubborn, and the medicine hasn't worked.[2]

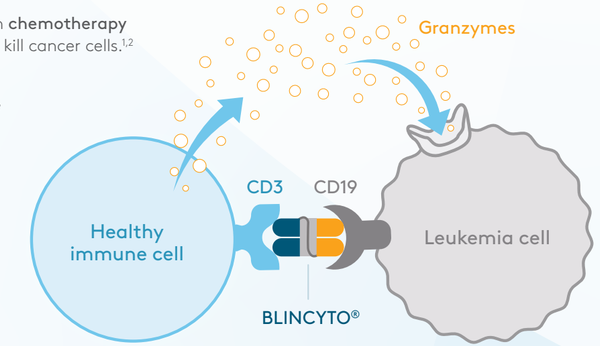


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BLINCYTO® uses the body's own immune system to fight leukemia[1]

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

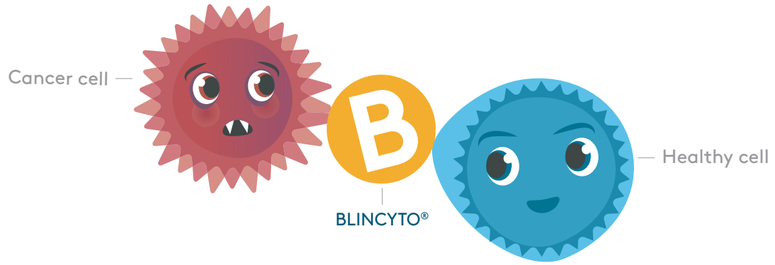
1. **Finds:** Cancer cells can hide from healthy immune cells. BLINCYTO® helps healthy immune cells find cancer cells and bring them together.[1,7]
2. **Activates:** When the healthy cells and cancer cells are connected, BLINCYTO® activates the healthy immune cells to release specialized proteins called granzymes.[7]
3. **Kills:** The granzymes then attack and kill the cancer cells.[7]



Read on to see how adding BLINCYTO® after initial treatment (consolidation) can help people with ALL

Talk to Kids

BLINCYTO® is a medicine your doctor may use to treat your leukemia. It is different from chemotherapy. It works with the cells in the body. BLINCYTO® helps the healthy cells find and get rid of some of the cancer cells.[1,2]



IMPORTANT SAFETY INFORMATION

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
- have Down Syndrome
- have an infection

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BLINCYTO® can help people who have ALL—including those who are MRD–positive[8]

BLINCYTO® is a prescription medicine used to treat adults and children 1 month and older with:[8]

- B-cell precursor (BCP) acute lymphoblastic leukemia (ALL) in remission when only a small number of cancer cells remain in the body (MRD)
- 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

It is not known if BLINCYTO® is safe and effective in children less than 1 month of age.[8]

IMPORTANT SAFETY INFORMATION

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

- 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.

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

BLINCYTO® can also help people who are MRD-negative after initial treatment[1,5]

In a study of 224 adults with BCP-ALL who tested MRD–negative, half were given BLINCYTO® and chemotherapy. The other half were given only chemotherapy.[1,5]

Adding BLINCYTO® to chemotherapy after initial treatment helped adults who were MRD-negative live longer at 3 years than those treated with chemotherapy alone.[1,5]

- At 3 years, 85% of the people who received BLINCYTO® and chemotherapy were alive vs 69% of the people who received chemotherapy only[1]

See more details on the next page

Talk to Kids

Even though you may feel better after initial chemotherapy, your doctor may test you to see if you have a small amount of cancer left. Whether or not you have a small amount of cancer left, BLINCYTO® is a medicine that can be used with chemotherapy to help you live longer.[1,2,4,6]*

*Based on the data described above.[1,5]



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Adding BLINCYTO® after initial treatment helped people live longer when used with chemotherapy[1]

In a study of 224 people aged 30–70 years with newly diagnosed Philadelphia chromosome–negative [Ph(–)] BCP-ALL, half were given BLINCYTO® and chemotherapy. The other half were given only chemotherapy.[1]

At 3 years, treatment with BLINCYTO® and chemotherapy **helped people live longer** vs chemotherapy alone[1,*]



85% **of people on BLINCYTO® + chemotherapy were still alive at 3 years** (out of 112 people)

vs



69% of people on chemotherapy alone were still alive at 3 years (out of 112 people)



In this study, most (57%) people were given 4 cycles of BLINCYTO®.[9]
Your doctor will decide how long you or your child will stay on treatment.

The use of BLINCYTO® after initial treatment (consolidation) in patients one month and older with Ph(–) BCP-ALL is supported by data from the study above and 2 additional studies:[1]

- Study of BLINCYTO® in consolidation in people aged 28 days to 18 years with Ph(–) BCP-ALL in first relapse[1]
- Study of BLINCYTO® in consolidation in people aged 1–27 years with Ph(–) BCP-ALL in first relapse[10]

*This analysis looked at survival for a median follow-up of 3.6 years, and the proportion of people alive at 3 years was estimated.[1]

Please see additional Important Safety Information, including **BOXED WARNINGS**, for BLINCYTO® on pages 22–23.

Adding BLINCYTO® after initial treatment helped children live cancer-free longer when used with chemotherapy[6]

In a study that included 1,440 children aged 1 to less than 10 years, 718 were given both BLINCYTO® and chemotherapy in the consolidation phase of chemotherapy. The rest were given only chemotherapy.[6]

At 3 years, treatment with BLINCYTO® and chemotherapy **helped children live cancer-free longer** vs chemotherapy alone[6,*]



96% **of people on BLINCYTO® + chemotherapy were living cancer-free at 3 years** (out of 718 children)

vs



88% of people on chemotherapy alone were living cancer-free at 3 years (out of 722 children)

- This study included 32 children who had Down Syndrome (16 received BLINCYTO® + chemotherapy, and 16 received chemotherapy only)[6]
  - 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[1]

Results of this study in children were consistent with results in people aged 30–70 years, as shown on the previous page.[1,6]

*Children were followed for an average of 2.5 years in this study.[1,6]

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®.

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How BLINCYTO® is given

BLINCYTO® is given by a continuous **intravenous (IV) infusion**. This means the medicine goes into a vein and then goes into the blood. The dosing of BLINCYTO® occurs in cycles. Here's how a cycle works:[1,2]



One cycle is 4 weeks of infusion followed by 2 weeks without infusion. Your doctor will decide how long you will need to stay on 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:

- 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.

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

BLINCYTO® is available in infusion bags that deliver your medicine continuously over time[1]

Your doctor may help decide which bag schedule is best for you based on a variety of factors (eg, age, lifestyle, caregiver support, distance to care center, and overall mobility).[1,8,11]

BLINCYTO® is available in 5 infusion bags

24 hours	48 hours	72 hours	96 hours	7 days
1 day	2 days	3 days	4 days	1 week

Talk to Kids



How does BLINCYTO® work?

BLINCYTO® comes in a bag. It will be connected by a tube and needle. BLINCYTO® will be given by continuous IV infusion for 4 weeks, followed by a 2-week break during which you will not receive BLINCYTO®.[8]

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BLINCYTO® timeline after initial treatment (consolidation)

Treatment with BLINCYTO® starts in the hospital to make sure that it is safe and to watch for any side effects that may occur.[8]

- Your health care provider will provide a medicine to help reduce the likelihood of infusion reactions, which are common with BLINCYTO®
- Your health care provider will monitor for and treat any serious reactions to BLINCYTO® if they happen

One cycle of BLINCYTO® treatment is 28 days (4 weeks)[8]

CYCLE 1 First 3 days* **in-patient**[8]

CYCLE 2* First 2 days **in-patient**[8]

The remaining days of the cycle may be out-patient, as determined by your health care provider[8]

- After the hospital stay, your doctor will decide if the rest of the treatment can be given at home with a small portable pump[8]
- Your doctor may refer you to an outpatient clinic or an infusion center to manage treatment[8]
- The medicine will need to be refilled every 24 hours, 48 hours, 72 hours, 96 hours, or 7 days by a health care professional[1,8]
- If additional treatment cycles of BLINCYTO® are necessary or if treatment is stopped for a period of time and restarted, treatment may also be provided in a hospital or clinic.[8]

*3 days are recommended when BLINCYTO® is added after initial treatment (during the consolidation phase). Your doctor will determine how many days you will spend in the hospital and the number of BLINCYTO® treatment cycles you will need.[1,8]

Talk to Kids

Can BLINCYTO® be given at home?

BLINCYTO® is started in the hospital because your doctor wants to make sure you are safe. Your doctor may decide that BLINCYTO® can be continued at home, if that is right for you. If your doctor decides this, you will learn about what happens next from your doctor. It's possible a nurse may come to help you with the medicine.[8]

Please see additional Important Safety Information, including **BOXED WARNINGS**, for BLINCYTO® on pages 22–23.

Receiving BLINCYTO® at home

If it feels overwhelming to receive BLINCYTO® away from the hospital, try not to worry. Your health care team may be able to help you. They will make sure you are prepared.

Here are some ways to ensure your safety and feel confident when BLINCYTO® is given at home:

- Talk to your health care provider about whether the IV bag will be changed at an outpatient center or by a home health care provider
- Call your doctor if there are any problems or side effects
- Do not change the settings on the pump, even if the alarm sounds. Any setting changes may cause a dosing error[8]
- If there are any problems with the pump or the pump alarm sounds, contact your health care provider immediately[8]
- If tubing detaches or if you detect leakage from your pump or bag, contact your health care provider immediately
- Keep BLINCYTO® and all medicines out of the reach of other children in the household

Your health care provider will explain how to store and dispose of BLINCYTO® and used supplies.

IMPORTANT SAFETY INFORMATION

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.

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Possible side effects[8]

BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death. These include: cytokine release syndrome (CRS), infusion reactions, and neurologic problems.

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
- Skin rash

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
- Tremors

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.

Call your health care provider for medical advice about side effects.

Please see additional Important Safety Information, including **BOXED WARNINGS**, for BLINCYTO® on pages 22–23.

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
- 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 the following serious side effects:

- 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 the FDA at 1-800-FDA-1088.

Tell your health care provider right away if you develop an infection or fever, or if you develop any other side effects that are bothersome or do not go away

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

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Questions to consider for your care team

BLINCYTO® is a treatment option for some children or teenagers who have ALL.[8] This page includes some common questions you might have about BLINCYTO®. Use the questions below to talk to your doctor about your BLINCYTO® treatment.

? Questions for you to ask your doctor or health care provider

What is BLINCYTO®?

- Why am I getting BLINCYTO®?
- How does BLINCYTO® work?
- What is the difference between BLINCYTO® and other treatments?
- How has BLINCYTO® helped other children with ALL?

Taking BLINCYTO®

- How will I receive BLINCYTO®?
- What are possible side effects with BLINCYTO® ?
- When will my treatment start?
- How long will my treatment last?

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

For patients receiving BLINCYTO® outside of the hospital*

- How will BLINCYTO® affect daily activities, like going to school, sleeping, or spending time with friends?

*As determined by your health care team, patients may be able to receive BLINCYTO® outside of the hospital.

The infusion bag and pump

- Who will change my infusion bag?
- How do I bathe/shower with my infusion bag?
- Any tips for keeping the dressing around the infusion port dry?
- Who do I call if there's a problem with my infusion bag?

For caregivers:

- Are there any support groups?
- Is BLINCYTO® covered by our insurance?
- How is it decided whether we get a home health care nurse?
- Are there any assistance programs?

IMPORTANT SAFETY INFORMATION

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.

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With personalized solutions, Amgen SupportPlus is here to help

AMGEN® Support+

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.

Outpatient Therapy Support

Eligible pediatric patients may receive a medical backpack to help support the transition to outpatient therapy.

Amgen SupportPlus

Call 866-264-2778 Monday to Friday, 8:30 AM to 8:00 PM ET, or visit www.AmgenSupportPlus.com to learn how Amgen can help.

*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.

Please see additional Important Safety Information, including **BOXED WARNINGS**, for BLINCYTO® on pages 22–23.

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 personal caregivers, there are patient support groups that can provide invaluable support throughout the treatment process, such as:

- The American Childhood Cancer Organization at acco.org
- The Children's Oncology Group at childrensoncologygroup.org
- Blood Cancer United at bloodcancerunited.org
- Stupid Cancer at stupidcancer.org
- Madelyn James Foundation at madelynjames.org

These third-party resources are for your information only. The organizations listed have not endorsed Amgen or any of its respective products and services. Amgen does not endorse and is not responsible for the content included in these resources.

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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.
    - **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 and may be given anti-seizure medicine before starting 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
- 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.
- **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 healthcare 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
  - Muscle, joint, and bone pain
  - Low white blood cell count (neutropenia)
  - Nausea
  - 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 accompanying BLINCYTO® full Prescribing Information, including BOXED WARNINGS and Medication Guide.

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial



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 March 4, 2026. **3.** Children's Hospital of Philadelphia. Acute Lymphoblastic Leukemia (ALL). https://www.chop.edu/conditions-diseases/acute-lymphoblastic-leukemia-all. Accessed March 4, 2026. **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.** Litzow MR, Sun Z, Mattison RJ, et al. Blinatumomab for MRD-negative acute lymphoblastic leukemia in adults. *N Engl J Med*. 2024;391:320-333. **6.** Gupta S, Rau RE, Kairalla JA, et al. Blinatumomab in standard-risk B-cell acute lymphoblastic leukemia in children. *N Engl J Med*. 2025;392:875-891. **7.** Nagorsen D, Baeuerle PA. Immunomodulatory therapy of cancer with T cell-engaging BiTE antibody blinatumomab. *Exp Cell Res*. 2011;317:1255-1260. **8.** BLINCYTO® (blinatumomab) medication guide, Amgen. **9.** Data on file, Amgen; 2021. **10.** Brown PA, Ji L, Xu X, et al. Effect of postreinduction therapy consolidation with blinatumomab vs chemotherapy on disease-free survival in children, adolescents, and young adults with first relapse of B-cell acute lymphoblastic leukemia: a randomized clinical trial. *JAMA*. 2021;325:833-842. **11.** Zupanec S, Beauchemin M, Rau RE. Navigating B-ALL in the Era of Blinatumomab. *Am Soc Clin Oncol Educ Book*. May 2025;45:e472778. DOI 10.1200/EDBK-25-4727.

Please see accompanying BLINCYTO® full Prescribing Information, including BOXED WARNINGS and Medication Guide.

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USA-103-82259 05/26

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

If you've had initial therapy and are now in the next phase of treatment

Treat your B-cell precursor ALL with BLINCYTO®[1]

A guide for children, teenagers, and their caregivers



Not an actual patient.

ALL, acute lymphoblastic leukemia.

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.

Please see additional Important Safety Information, including **BOXED WARNINGS** and Medication Guide, for BLINCYTO® on pages 22–23.

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Talk to Kids

Hello! I'm here to help you talk about ALL and BLINCYTO® to kids.

Look for this special boxed feature as you read through this brochure.

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

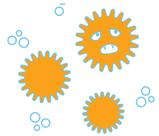
What is ALL?

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]

Talk to Kids

What does it mean to have ALL?

ALL is a type of sickness, called cancer, in the blood. There are different types of cells in the blood. Some are healthy, but other cells can become sick and are called cancer cells. The number of cancer cells can grow and cause problems for the healthy cells.[2,3]



IMPORTANT SAFETY INFORMATION

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

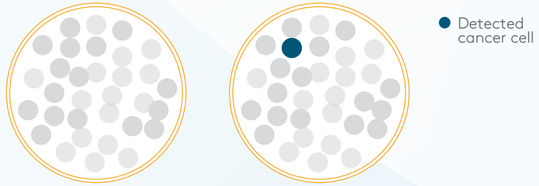
- Call your health care provider or get emergency medical help right away if you get any of the symptoms listed below:
  - **BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death, including:**
    - **Neurologic problems.** Symptoms of neurologic problems may 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 and may be given anti-seizure medicine before starting 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® (blinatumomab) for injection
35 mcg single-dose vial

What happens when ALL is treated?

After being treated for ALL, a few different things can happen:

- You may achieve **remission**. This means that signs and symptoms of cancer have decreased or disappeared[2,4]
- Remission is a great achievement, but it does not always mean the cancer is completely gone, as small amounts of disease may still remain[2,4]
- Your doctor may test you for "minimal residual disease", or **MRD**[4]
  - **MRD-negative** means no cancer cells can be detected. However, there could still be some underlying disease.[2,4]
  - **MRD-positive** means there are a relatively small number of cancer cells remaining[2,4]



- Even after you become MRD-negative, your doctor may give you more medicine to help you stay in remission longer[5,6]
- Sometimes leukemia cells or signs and symptoms of cancer can return. This is called a **relapse**[2]
- You may be treated and never reach remission. In this case, the cancer is called **refractory** disease[2]

IMPORTANT SAFETY INFORMATION

Who should not receive BLINCYTO®?

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

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

Talk to Kids

Remission means that the signs and symptoms of your cancer have decreased or disappeared, and you may be feeling better.[2]

Even if you're feeling better after initial chemotherapy, your doctor may still do tests to see if the cancer is gone. More medicine may be needed to help keep you feeling well and prevent the cancer from coming back.[2,4-6]

Relapse means your cancer has come back.[2]

Refractory means your cancer is stubborn, and the medicine hasn't worked.[2]

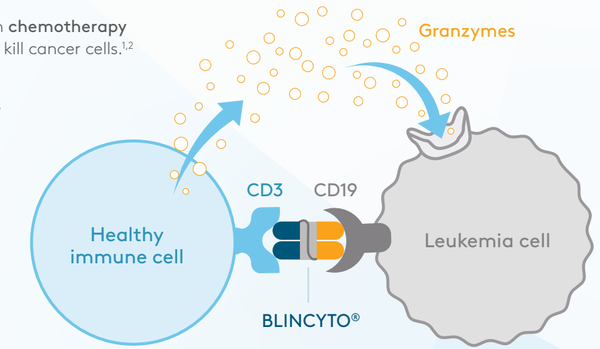


BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

BLINCYTO® uses the body's own immune system to fight leukemia[1]

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

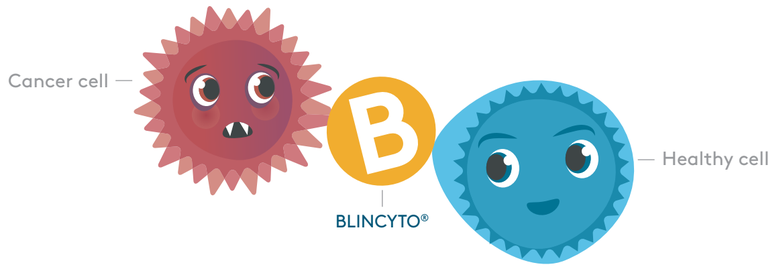
1. **Finds:** Cancer cells can hide from healthy immune cells. BLINCYTO® helps healthy immune cells find cancer cells and bring them together.[1,7]
2. **Activates:** When the healthy cells and cancer cells are connected, BLINCYTO® activates the healthy immune cells to release specialized proteins called granzymes.[7]
3. **Kills:** The granzymes then attack and kill the cancer cells.[7]



Read on to see how adding BLINCYTO® after initial treatment (consolidation) can help people with ALL

Talk to Kids

BLINCYTO® is a medicine your doctor may use to treat your leukemia. It is different from chemotherapy. It works with the cells in the body. BLINCYTO® helps the healthy cells find and get rid of some of the cancer cells.[1,2]



IMPORTANT SAFETY INFORMATION

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
- have Down Syndrome
- have an infection

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

BLINCYTO® can help people who have ALL—including those who are MRD–positive[8]

BLINCYTO® is a prescription medicine used to treat adults and children 1 month and older with:[8]

- B-cell precursor (BCP) acute lymphoblastic leukemia (ALL) in remission when only a small number of cancer cells remain in the body (MRD)
- 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

It is not known if BLINCYTO® is safe and effective in children less than 1 month of age.[8]

IMPORTANT SAFETY INFORMATION

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

- 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.

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

BLINCYTO® can also help people who are MRD-negative after initial treatment[1,5]

In a study of 224 adults with BCP-ALL who tested MRD–negative, half were given BLINCYTO® and chemotherapy. The other half were given only chemotherapy.[1,5]

Adding BLINCYTO® to chemotherapy after initial treatment helped adults who were MRD-negative live longer at 3 years than those treated with chemotherapy alone.[1,5]

- At 3 years, 85% of the people who received BLINCYTO® and chemotherapy were alive vs 69% of the people who received chemotherapy only[1]

See more details on the next page

Talk to Kids

Even though you may feel better after initial chemotherapy, your doctor may test you to see if you have a small amount of cancer left. Whether or not you have a small amount of cancer left, BLINCYTO® is a medicine that can be used with chemotherapy to help you live longer.[1,2,4,6]*

*Based on the data described above.[1,5]



BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

Adding BLINCYTO® after initial treatment helped people live longer when used with chemotherapy[1]

In a study of 224 people aged 30–70 years with newly diagnosed Philadelphia chromosome–negative [Ph(–)] BCP-ALL, half were given BLINCYTO® and chemotherapy. The other half were given only chemotherapy.[1]

At 3 years, treatment with BLINCYTO® and chemotherapy **helped people live longer** vs chemotherapy alone[1,*]



85% **of people on BLINCYTO® + chemotherapy were still alive at 3 years** (out of 112 people)

vs



69% of people on chemotherapy alone were still alive at 3 years (out of 112 people)



In this study, most (57%) people were given 4 cycles of BLINCYTO®.[9]
Your doctor will decide how long you or your child will stay on treatment.

The use of BLINCYTO® after initial treatment (consolidation) in patients one month and older with Ph(–) BCP-ALL is supported by data from the study above and 2 additional studies:[1]

- Study of BLINCYTO® in consolidation in people aged 28 days to 18 years with Ph(–) BCP-ALL in first relapse[1]
- Study of BLINCYTO® in consolidation in people aged 1–27 years with Ph(–) BCP-ALL in first relapse[10]

*This analysis looked at survival for a median follow-up of 3.6 years, and the proportion of people alive at 3 years was estimated.[1]

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

Adding BLINCYTO® after initial treatment helped children live cancer-free longer when used with chemotherapy[6]

In a study that included 1,440 children aged 1 to less than 10 years, 718 were given both BLINCYTO® and chemotherapy in the consolidation phase of chemotherapy. The rest were given only chemotherapy.[6]

At 3 years, treatment with BLINCYTO® and chemotherapy **helped children live cancer-free longer** vs chemotherapy alone[6,*]



96% **of people on BLINCYTO® + chemotherapy were living cancer-free at 3 years** (out of 718 children)

vs



88% of people on chemotherapy alone were living cancer-free at 3 years (out of 722 children)

- This study included 32 children who had Down Syndrome (16 received BLINCYTO® + chemotherapy, and 16 received chemotherapy only)[6]
  - 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[1]

Results of this study in children were consistent with results in people aged 30–70 years, as shown on the previous page.[1,6]

*Children were followed for an average of 2.5 years in this study.[1,6]

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®.

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

How BLINCYTO® is given

BLINCYTO® is given by a continuous **intravenous (IV) infusion**. This means the medicine goes into a vein and then goes into the blood. The dosing of BLINCYTO® occurs in cycles. Here's how a cycle works:[1,2]



One cycle is 4 weeks of infusion followed by 2 weeks without infusion. Your doctor will decide how long you will need to stay on 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:

- 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.

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

BLINCYTO® is available in infusion bags that deliver your medicine continuously over time[1]

Your doctor may help decide which bag schedule is best for you based on a variety of factors (eg, age, lifestyle, caregiver support, distance to care center, and overall mobility).[1,8,11]

BLINCYTO® is available in 5 infusion bags

24 hours	48 hours	72 hours	96 hours	7 days
1 day	2 days	3 days	4 days	1 week

Talk to Kids



How does BLINCYTO® work?

BLINCYTO® comes in a bag. It will be connected by a tube and needle. BLINCYTO® will be given by continuous IV infusion for 4 weeks, followed by a 2-week break during which you will not receive BLINCYTO®.[8]

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

BLINCYTO® timeline after initial treatment (consolidation)

Treatment with BLINCYTO® starts in the hospital to make sure that it is safe and to watch for any side effects that may occur.[8]

- Your health care provider will provide a medicine to help reduce the likelihood of infusion reactions, which are common with BLINCYTO®
- Your health care provider will monitor for and treat any serious reactions to BLINCYTO® if they happen

One cycle of BLINCYTO® treatment is 28 days (4 weeks)[8]



First 3 days*
in-patient[8]



First 2 days
in-patient[8]

The remaining days of the cycle may be out-patient, as determined by your health care provider[8]

- After the hospital stay, your doctor will decide if the rest of the treatment can be given at home with a small portable pump[8]
- Your doctor may refer you to an outpatient clinic or an infusion center to manage treatment[8]
- The medicine will need to be refilled every 24 hours, 48 hours, 72 hours, 96 hours, or 7 days by a health care professional[1,8]
- If additional treatment cycles of BLINCYTO® are necessary or if treatment is stopped for a period of time and restarted, treatment may also be provided in a hospital or clinic.[8]

*3 days are recommended when BLINCYTO® is added after initial treatment (during the consolidation phase). Your doctor will determine how many days you will spend in the hospital and the number of BLINCYTO® treatment cycles you will need.[1,8]

Talk to Kids



Can BLINCYTO® be given at home?

BLINCYTO® is started in the hospital because your doctor wants to make sure you are safe. Your doctor may decide that BLINCYTO® can be continued at home, if that is right for you. If your doctor decides this, you will learn about what happens next from your doctor. It's possible a nurse may come to help you with the medicine.[8]

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

Receiving BLINCYTO® at home

If it feels overwhelming to receive BLINCYTO® away from the hospital, try not to worry. Your health care team may be able to help you. They will make sure you are prepared.

Here are some ways to ensure your safety and feel confident when BLINCYTO® is given at home:

- Talk to your health care provider about whether the IV bag will be changed at an outpatient center or by a home health care provider
- Call your doctor if there are any problems or side effects
- Do not change the settings on the pump, even if the alarm sounds. Any setting changes may cause a dosing error[8]
- If there are any problems with the pump or the pump alarm sounds, contact your health care provider immediately[8]
- If tubing detaches or if you detect leakage from your pump or bag, contact your health care provider immediately
- Keep BLINCYTO® and all medicines out of the reach of other children in the household

Your health care provider will explain how to store and dispose of BLINCYTO® and used supplies.

IMPORTANT SAFETY INFORMATION

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® (blinatumomab) for injection
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Possible side effects[8]

BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death. These include: cytokine release syndrome (CRS), infusion reactions, and neurologic problems.

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
- Skin rash

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
- Tremors

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.

Call your health care provider for medical advice about side effects.

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

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
- 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 the following serious side effects:

- 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 the FDA at 1-800-FDA-1088.

Tell your health care provider right away if you develop an infection or fever, or if you develop any other side effects that are bothersome or do not go away

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

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Questions to consider for your care team

BLINCYTO® is a treatment option for some children or teenagers who have ALL.[8] This page includes some common questions you might have about BLINCYTO®. Use the questions below to talk to your doctor about your BLINCYTO® treatment.

? Questions for you to ask your doctor or health care provider

What is BLINCYTO®?

- Why am I getting BLINCYTO®?
- How does BLINCYTO® work?
- What is the difference between BLINCYTO® and other treatments?
- How has BLINCYTO® helped other children with ALL?

Taking BLINCYTO®

- How will I receive BLINCYTO®?
- What are possible side effects with BLINCYTO® ?
- When will my treatment start?
- How long will my treatment last?

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

For patients receiving BLINCYTO® outside of the hospital*

- How will BLINCYTO® affect daily activities, like going to school, sleeping, or spending time with friends?

*As determined by your health care team, patients may be able to receive BLINCYTO® outside of the hospital.

The infusion bag and pump

- Who will change my infusion bag?
- How do I bathe/shower with my infusion bag?
- Any tips for keeping the dressing around the infusion port dry?
- Who do I call if there's a problem with my infusion bag?

For caregivers:

- Are there any support groups?
- Is BLINCYTO® covered by our insurance?
- How is it decided whether we get a home health care nurse?
- Are there any assistance programs?

IMPORTANT SAFETY INFORMATION

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.

BLINCYTO® (blinatumomab) for injection
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With personalized solutions, Amgen SupportPlus is here to help

AMGEN® Support+

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.

Outpatient Therapy Support

Eligible pediatric patients may receive a medical backpack to help support the transition to outpatient therapy.

Amgen SupportPlus

Call 866-264-2778 Monday to Friday, 8:30 AM to 8:00 PM ET, or visit www.AmgenSupportPlus.com to learn how Amgen can help.

*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.

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.

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 personal caregivers, there are patient support groups that can provide invaluable support throughout the treatment process, such as:

- The American Childhood Cancer Organization at acco.org
- The Children's Oncology Group at childrensoncologygroup.org
- Blood Cancer United at bloodcancerunited.org
- Stupid Cancer at stupidcancer.org
- Madelyn James Foundation at madelynjames.org

These third-party resources are for your information only. The organizations listed have not endorsed Amgen or any of its respective products and services. Amgen does not endorse and is not responsible for the content included in these resources.

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

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.
    - **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 and may be given anti-seizure medicine before starting 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
- 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.
- **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 healthcare 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
  - Muscle, joint, and bone pain
  - Low white blood cell count (neutropenia)
  - Nausea
  - 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® full Prescribing Information, including BOXED WARNINGS and Medication Guide.

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

Please see additional Important Safety Information, including **BOXED WARNINGS,** for BLINCYTO® on pages 22–23.



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 March 4, 2026. **3.** Children's Hospital of Philadelphia. Acute Lymphoblastic Leukemia (ALL). https://www.chop.edu/conditions-diseases/acute-lymphoblastic-leukemia-all. Accessed March 4, 2026. **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.** Litzow MR, Sun Z, Mattison RJ, et al. Blinatumomab for MRD-negative acute lymphoblastic leukemia in adults. *N Engl J Med*. 2024;391:320-333. **6.** Gupta S, Rau RE, Kairalla JA, et al. Blinatumomab in standard-risk B-cell acute lymphoblastic leukemia in children. *N Engl J Med*. 2025;392:875-891. **7.** Nagorsen D, Baeuerle PA. Immunomodulatory therapy of cancer with T cell-engaging BiTE antibody blinatumomab. *Exp Cell Res*. 2011;317:1255-1260. **8.** BLINCYTO® (blinatumomab) medication guide, Amgen. **9.** Data on file, Amgen; 2021. **10.** Brown PA, Ji L, Xu X, et al. Effect of postreinduction therapy consolidation with blinatumomab vs chemotherapy on disease-free survival in children, adolescents, and young adults with first relapse of B-cell acute lymphoblastic leukemia: a randomized clinical trial. *JAMA*. 2021;325:833-842. **11.** Zupanec S, Beauchemin M, Rau RE. Navigating B-ALL in the Era of Blinatumomab. *Am Soc Clin Oncol Educ Book*. May 2025;45:e472778. DOI 10.1200/EDBK-25-4727.

Please see BLINCYTO® full Prescribing Information, including BOXED WARNINGS and Medication Guide.

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BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial