For children and teenagers who've had initial therapy and are now in the next phase of treatment.

Or if their cancer has returned or hasn't responded to treatment.



BLINCYTO® gives them a better chance against B-cell precursor ALL¹

A guide for children, teenagers, and their caregivers

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.

Not actual patient

Please see additional Important Safety Information, including **BOXED WARNINGS** and Medication Guide, for BLINCYTO® on pages 24-25.



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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}

What happens when ALL is treated?

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

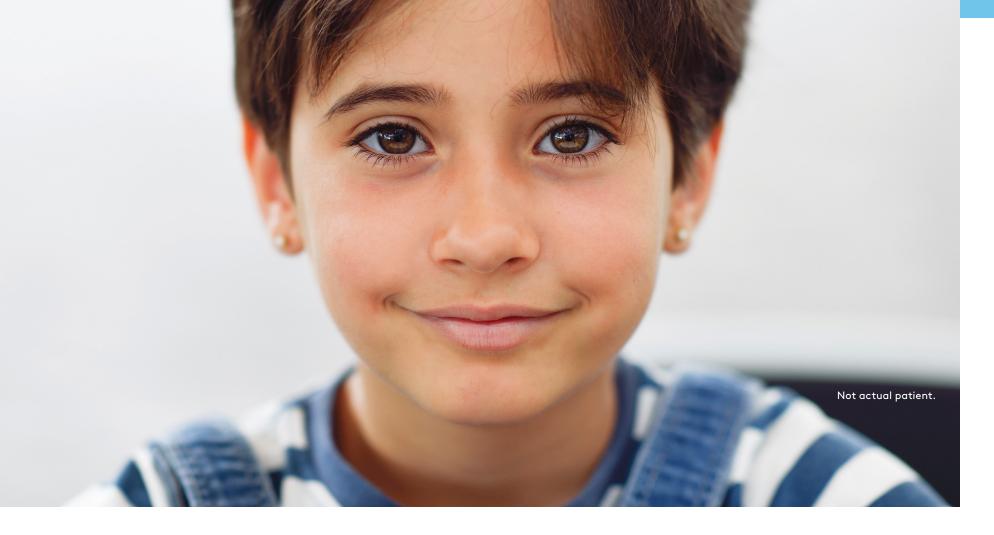
- Children may achieve **remission**. This means that all signs and symptoms of cancer have decreased or disappeared²
- Remission is a great achievement, but it does not always mean the cancer has been cured as there could be remaining traces of disease. This is called minimal residual disease, or MRD⁴
- People who do not have detectable traces of disease are referred to as MRD negative
- Sometimes cancer cells or signs and symptoms of cancer can return. This is called a **relapse**²
- Or a child may be treated and never reach remission. In this case, the cancer is called refractory disease²

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 over the age of 10 years 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.





What is BLINCYTO®?

BLINCYTO® is a prescription medicine used to treat B-cell precursor (BCP) ALL in adults and children. It is an **immunotherapy**, not a **chemotherapy**. An immunotherapy is a type of treatment that works with the body's own immune system to fight cancer. ²

How BLINCYTO® fights cancer



Infusion

BLINCYTO® is given by a continuous **infusion** into the vein. The medicine is designed to work with your immune system to fight cancer.^{1,2}



Find

There are healthy immune cells and cancer cells in your body. The cancer cells can hide from the healthy immune cells. BLINCYTO® helps the healthy immune cells find the cancer cells.¹⁻³



Engage

Now the healthy immune cell connects to the cancer cell. Once they are together, the healthy immune cell can help fight the cancer cell.^{1,2}

Read on to see how adding BLINCYTO® after initial treatment can help people with BCP-ALL¹

Show your child how BLINCYTO® works on page 23



IMPORTANT SAFETY INFORMATION

Who should not receive BLINCYTO®?

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



Adding BLINCYTO® after initial treatment helped people live longer when used with chemotherapy¹

BLINCYTO® was studied in 224 people aged 30-70 years with newly diagnosed Philadelphia chromosome-negative (Ph(-)) BCP-ALL. The study took place in the consolidation phase of chemotherapy. Of the 224 people, half were given both BLINCYTO® and chemotherapy. The other half were given only chemotherapy.

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



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

At 5 years, more people who received BLINCYTO® and chemotherapy were still alive vs chemotherapy alone^{1,5,†}

82% BLINCYTO® + chemotherapy

VS

63% Chemotherapy alone

(out of 112 people)









In this study, most people were given 4 cycles of BLINCYTO[®].⁶
Your doctor will decide how long you or your child will stay on treatment.

The use of BLINCYTO® after initial treatment 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 relapse¹
- Study of BLINCYTO® in consolidation in people aged 1–27 years with Ph(-) BCP-ALL in first relapse⁷

*This analysis looked at survival for an average of 3.6 years, and the proportion of people alive at 3 years was estimated.¹ ¹This analysis looked at survival for an average of 4.5 years, and the percentage of people alive at 5 years was estimated.¹.5

Please see additional Important Safety Information for BLINCYTO® on pages 24-25.



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® can help people who have MRD¹

In another trial, BLINCYTO® was studied in 86 people* with BCP-ALL who tested MRD positive after chemotherapy. This means that there were remaining cancer cells in their body. The goal was to become MRD-negative so there were no detectable traces of cancer left.^{1,4}

BLINCYTO® helped most people who were MRD positive become MRD negative^{1,†}

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



More than half were able to go on to 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 ever had an infusion reaction after receiving BLINCYTO® or other medications
- have a history of radiation treatment to the brain, or chemotherapy treatment



IMPORTANT SAFETY INFORMATION

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

• are scheduled to receive a vaccine. You should not receive a "live vaccine" for at least 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.



^{*} Adults ≥ 18 years old.¹

[†]As measured by a test that can detect 1 cancer cell out of 10,000 cells in the bone marrow.¹ (More sensitive testing methods may be able to detect lower levels of cancer cells.)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 this does not always mean the cancer is cured.\(^{1/2}\)

[§]One cycle of treatment with BLINCYTO® consists of 4 weeks of treatment followed by 2 weeks without treatment.1

^{** 59} out of 86 patients treated with BLINCYTO® in the study proceeded to a stem cell transplant.



BLINCYTO® can help people whose cancer has returned or did not respond to treatment¹

When cancer returns after a period of **remission**, this is called a **relapse**. When cancer does not respond to treatment, this is called **refractory** disease.²

In a study of 70 children (ranging in age from 7 months to 17 years) with relapsed or refractory BCP-ALL:1,*



Complete response means there were no signs of cancer after treatment and certain blood counts fully or partially recovered to normal within the first 2 treatment cycles.^{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:

- 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®.



^{*}Some people had more than one relapse before the study. Others may have had a relapse following a stem cell transplantation prior to getting BLINCYTO®, or for some their cancer may have been refractory to other treatments.¹



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

BLINCYTO® is given on one or more of the following time intervals: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.



What to expect when starting BLINCYTO®



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



Your health care provider may give BLINCYTO® in a hospital or clinic for the first 3 or 9 days of the first treatment cycle and for the first 2 days of the second cycle to check for side effects. 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



After the hospital stay, your doctor will decide if the rest of the treatment can be given at home with a small portable pump. Or 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, or 7 days by a health care professional.¹

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 child's 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



If there are any problems with the pump or the pump alarm sounds, 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.

Please see additional Important Safety Information for BLINCYTO® on pages 24–25.



Possible side effects⁸

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 over the age of 10 years may have a higher risk of seizures with BLINCYTO® treatment.

The most common side effects of BLINCYTO® include:8

- 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:8

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

These are not all the possible side effects of BLINCYTO[®]. ⁸

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

Tell your child's health care provider right away if your child develops an infection or fever, or if they develop any other side effects that are bothersome or do not go away⁸

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



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 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
- The Leukemia & Lymphoma Society at Ils.org
- Stupid Cancer at <u>stupidcancer.orq</u>

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.



Talking together about BLINCYTO®

What does it mean to have ALL?

ALL is a type of sickness, called cancer, in the blood and the bone marrow. 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 immune cells.^{2,3}

What is BLINCYTO®?

BLINCYTO® is a medicine that can help people get better. It works with the cells in the body. BLINCYTO® helps the healthy immune cells find the cancer cells so they can get rid of them.^{1,2}

How does BLINCYTO® work?

BLINCYTO® comes in a bag. It will be connected by a tube and needle. BLINCYTO® will be given for 4 weeks and taken off for 2 weeks.^{1,2}

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 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. 1.8

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.



WHAT IS BLINCYTO® (blinatumomab)?

BLINCYTO® is a prescription medicine used to treat adults and children 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 over the age of 10 years 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
- 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
- o 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.



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Glossary^{2,9}

Acute lymphoblastic leukemia (ALL): ALL is a type of cancer of the blood and bone marrow that affects white blood cells.

Chemotherapy: A treatment that uses chemical drugs to stop the replication 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 traditional diagnostic techniques.

Refractory: When a disease does not respond to treatment. It may be resistant at the beginning of treatment, or it may become resistant during 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 of cancer have decreased or disappeared. This does not always mean that 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 July 3, 2023. 3. Children's Hospital of Philadelphia. Acute Lymphoblastic Leukemia (ALL). https://www.chop.edu/conditions-diseases/acute-lymphoblastic-leukemia-all. Accessed July 3, 2023. 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. Data on file, Amgen; [1]; 2021. 6. Data on file, Amgen; [2]; 2021. 7. 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. 8. BLINCYTO® (blinatumomab) medication guide, Amgen. 9. 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.

Please see BLINCYTO® full Prescribing Information including Medication Guide.



