INDICATION
BLINCYTO® (blinatumomab) is a prescription medication used to treat Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

More clinical studies are needed to verify the benefit of BLINCYTO® in order to continue its FDA approval.

IMPORTANT SAFETY INFORMATION
The most important information about BLINCYTO®:

• Call your health care provider or get emergency medical help right away if you get any of the symptoms listed in this brochure.

• Using BLINCYTO® may cause serious side effects that can be severe, life-threatening, or lead to death, including:
  – Cytokine Release Syndrome (CRS) and Infusion Reactions
  – Neurologic problems

Please see the Important Safety Information for BLINCYTO® on pages 15-16. Click here to view the full Prescribing Information including Medication Guide.
INTRODUCTION

How Can This Guide Help You?
If your doctor has just prescribed BLINCYTO®, you probably have some questions.

What is this treatment?
How is it different?
What should I expect?

This guide is here to help answer your questions, and explain what treatment with BLINCYTO® may be like for you.

Please see the Important Safety Information for BLINCYTO® on pages 15-16.
IMPORTANT SAFETY INFORMATION

Using 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
• low blood pressure
• face swelling
• tiredness or weakness
• nausea
• wheezing or trouble breathing
• dizziness
• vomiting
• skin rash
• headache
• chills
• face swelling

WHAT IS ACUTE LYMPHOBLASTIC LEUKEMIA?

Acute lymphoblastic leukemia (ALL) is a cancer of the blood in which a particular kind of white blood cell grows out of control.

Many patients achieve remission after they are first treated for ALL. That means that all signs and symptoms of cancer have disappeared. But sometimes, cancer cells can return after a patient is treated and cause a relapse. In other cases, a patient may be treated and never reach remission; this is referred to as refractory disease.

WHY YOUR DOCTOR CHOSE BLINCYTO® THERAPY

BLINCYTO® treats Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor ALL. It is an immunotherapy, not a chemotherapy. An immunotherapy is a type of treatment that engages with parts of your body’s own immune system. If your doctor has prescribed you BLINCYTO®, it may be because you’ve tried other treatments and didn’t reach remission, or relapsed.

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

For a complete list of ingredients, please click here to view the Medication Guide for BLINCYTO®.

Note: the active and inactive ingredients in BLINCYTO® are listed on the last page of the Medication Guide.

DID YOU KNOW

40% to 50% of adults with ALL may experience a relapse.

BLINCYTO® provides a way to treat adults with Ph- relapsed or refractory B-cell precursor ALL.

IMPORTANT SAFETY INFORMATION

Using 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
• skin rash

Please see the Important Safety Information for BLINCYTO® on pages 15-16.
GOALS OF YOUR TREATMENT

What We Are Working Towards

The main goal for many patients is to reach complete remission. Complete remission is reached when all test results show no signs of cancer and your blood counts have recovered.

The aggressive nature of Ph- relapsed or refractory B-cell precursor ALL may create a challenging road for those trying to reach this goal.

DID YOU KNOW

BLINCYTO® is an immunotherapy, a type of treatment that actually engages with parts of your body’s own immune system.

How Have Other Patients Responded?

In a large clinical study, 185 patients with Ph- relapsed or refractory B-cell precursor ALL were treated with BLINCYTO®.

60 patients out of the 185 studied reached complete remission meaning no signs of cancer were seen, and certain blood counts returned to normal.

17 patients out of the 185 studied reached complete remission with partial hematological recovery meaning no signs of cancer were seen, but certain blood counts did not completely return to normal.

Before participating in this study, many of these patients relapsed early and some even multiple times.

IMPORTANT SAFETY INFORMATION

Using 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
• confusion and disorientation
• loss of balance

41.6%

77 of 185 patients studied responded to BLINCYTO® treatment
GETTING STARTED

Designing Your Treatment Plan

Before you start BLINCYTO®, your doctor will design a treatment plan specifically for you.

Make sure to talk to your doctor about:

• All medical conditions, including any history of neurological problems like:
  • Seizures, confusion, trouble speaking, or loss of balance

• All of the medications you’re currently taking, including:
  • Prescription medicines, over-the-counter medicines, vitamins, and herbal supplements
  • Any infections you may have
  • Whether you’ve ever had an infusion reaction after receiving BLINCYTO® or other medications

• If you’re pregnant, become pregnant, or planning to become pregnant, since BLINCYTO® may harm unborn children

• If you’re breastfeeding or plan to breastfeed. It is not known if BLINCYTO® passes into your breast milk. You and your health care provider should decide if you will take BLINCYTO® or breastfeed. You should not do both.

• Insurance coverage

It may also be a good idea to keep a list of all the medications you take, so you can share them with your health care provider when you get a new medication.

IMPORTANT SAFETY INFORMATION

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 the Important Safety Information for BLINCYTO® on pages 15-16.

Where Will You Be Treated?

To monitor you for side effects, your health care provider may treat you with BLINCYTO® in a hospital or clinic for:

• The first 9 days of your first treatment cycle
• The first 2 days of your second treatment cycle

If you receive additional treatment cycles, or if your treatment is stopped for 4 or more hours, you may also be treated in a hospital or clinic in order to be supervised by a health care provider.

Depending on your treatment plan, your doctor may allow you to continue treatment with BLINCYTO® at:

Outpatient Clinic
Satellite Infusion Center
Home

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 symptoms of an infection such as a fever.
How Will You Receive BLINCYTO®?

BLINCYTO® will be given to you by intravenous (IV) infusion into your vein by an infusion pump. The pump should be programmable, lockable, and have an alarm. Additionally, you will have an IV bag.

Before you receive BLINCYTO®, you will also be given a corticosteroid medicine, a hormone used to help reduce the likelihood of infusion reactions.

Your Treatment Cycle

One treatment cycle lasts for 4 weeks, followed by a 2-week break with no BLINCYTO® infusions.

Before you receive BLINCYTO®, you will also be given a corticosteroid medicine, a hormone used to help reduce the likelihood of infusion reactions.

What You Should Know About Your Treatment

• You may receive up to 5 treatment cycles
• Your IV bag should be changed every 24 or 48 hours depending on your dosing schedule
• Blood tests will be performed during your treatment to check for side effects
• It’s important to keep the area around your IV catheter clean to reduce risk of infection (your health care provider will show you how to care for your catheter site)
• Do not drive, operate heavy machinery, or do other dangerous activities, since BLINCYTO® can cause neurological symptoms like dizziness, seizures, and confusion

IMPORTANT SAFETY INFORMATION

• 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. Tell your health care provider right away if you get a fever.

Please see the Important Safety Information for BLINCYTO® on pages 15-16.
You May Be Able to Go Home With Your Treatment

If your doctor decides you’re ready to go home with BLINCYTO®:

• Work with your nurse or social worker to determine whether you will be treated at home or a nearby outpatient center
• Talk to your health care provider about whether your bag will be changed at an outpatient clinic or with a home health care agency
• Assess your benefit coverage for outpatient treatment
• Carefully monitor yourself for side effects
• Call your doctor immediately if you experience any problems
• Keep BLINCYTO® and all medicines out of the reach of children
• Fill out the medical information card at the back of this guide in case of an emergency

GETTING STARTED

How to Store BLINCYTO®

• IV bags containing BLINCYTO® will arrive in a special package
• Do not open the package
• Do not freeze the package
• Your health care provider will open the package and store it in the refrigerator at 36°F to 46°F (2°C to 8°C) for up to 8 days
• Do not throw BLINCYTO® away in your household trash
• Ask your health care provider about disposing of BLINCYTO® and used supplies

IMPORTANT SAFETY INFORMATION

• Abnormal liver blood test. Your health care provider will do blood tests before you start BLINCYTO® and during treatment with BLINCYTO® to check your liver.

Please see the Important Safety Information for BLINCYTO® on pages 15-16.
SAFETY & SIDE EFFECTS

Serious Side Effects

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

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
- Skin rash

Neurologic problems. Symptoms of neurologic problems may include:
- Seizures
- Difficulty in speaking or slurred speech
- Loss of consciousness
- Confusion and disorientation
- Loss of balance

Tell your health care provider right away if you develop an infection or a fever. For more information about possible side effects, see the full Important Safety Information on pages 15-16.

Please see the Important Safety Information for BLINCYTO® on pages 15-16.

Serious Side Effects (continued)
- Infections: BLINCYTO® may cause life-threatening infections that may lead to death
- Low white blood cell counts (neutropenia): Neutropenia is common, and may sometimes be life-threatening. Low white blood cell counts can increase your risk of infection

Most Common Side Effects
- Fever
- Swelling of hands, ankles, or feet
- Constipation
- Shaking (tremor)
- Rash
- Skin rash
- Headache
- Nausea
- Diarrhea

While being treated with BLINCYTO®, your health care provider will check you for any of these problems. If you experience certain side effects, your health care provider may change your dose, delay, or completely stop your treatment.

IMPORTANT SAFETY INFORMATION

Tell your health care provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of BLINCYTO®.

Make sure to contact your doctor immediately if you experience any side effects while taking BLINCYTO®.
IMPORTANT SAFETY INFORMATION

The most important information about BLINCYTO®:

Call your health care provider or get emergency medical help right away if you get any of the symptoms listed below.

Using 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
- headache
- low blood pressure
- vomiting
- wheezing or trouble breathing
- tiredness or weakness
- chills
- skin rash
- dizziness
- nausea
- face swelling

Neurologic problems. Symptoms of neurologic problems may include:

- seizures
- confusion and disorientation
- difficulty in speaking or slurred speech
- loss of consciousness
- loss of balance
- face swelling

Your health care provider will check with you for these problems during treatment with BLINCYTO®. Your health care provider may temporarily stop or completely stop your treatment with BLINCYTO® if you have severe side effects.

Do not receive BLINCYTO® if you are allergic to blinatumomab or to any of the ingredients of 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 symptoms of an infection such as a fever.
- 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. Tell your health care provider right away if you get a fever.
- Abnormal liver blood test. Your health care provider will do blood tests before you start BLINCYTO® and during treatment with BLINCYTO® to check your liver.

Your health care provider will do blood tests during treatment to check for side effects.

The most common side effects of BLINCYTO® include fever, headache, swelling of hands, ankles or feet, nausea, constipation, shaking (tremor), rash, and diarrhea.

Tell your health care provider if you have any side effect that bothers you or that does not go away.

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

Please click here to view the medication guide for BLINCYTO® for discussion with your doctor.

Call your doctor for medical advice about side effects. You are encouraged to report side effects to the FDA at 1-800-FDA-1088 or visit: www.fda.gov/medwatch.
MEDICAL INFORMATION CARD

Because Ph- relapsed or refractory B-cell precursor ALL is a serious condition, it’s important for you to have quick and easy access to your medical contacts and information. Please fill out this card, and keep it handy at all times.

Building a Personal Support Network

Health care providers should be only one part of your support network. The support of family and friends is just as valuable. It may even be a good idea to ask a close family member or friend to be your care partner.

Once you’ve chosen a care partner, make sure that person also has the information from your Medical Information Card.
If you would like more information about BLINCYTO® (blinatumomab), talk with your health care provider. You can also ask your pharmacist or health care provider for information about BLINCYTO® that is written for health professionals.

For more information, go to www.blincyto.com or call Amgen at 1-800-772-6436.

Please click here to view the full Prescribing Information for BLINCYTO® including Medication Guide.
For more information, call Amgen at 1-800-772-6436.

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