PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BLINCYTO® powder for concentrate and solution for infusion

Blinatumomab

Read all of this leaflet carefully before you are given BLINCYTO®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- If you experience any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What BLINCYTO® is and what it is used for

2. What you need to know before you use BLINCYTO®

3. How to use BLINCYTO®

4. Possible side effects

5. How to store BLINCYTO®

6. Contents of the pack and other information

1. What BLINCYTO® is and what it is used for

The active ingredient in BLINCYTO® is blinatumomab.

BLINCYTO® is used to treat adults, adolescents, and children with acute lymphoblastic leukaemia. Acute lymphoblastic leukaemia is a cancer of the blood in which a particular kind of white blood cell is growing out of control. This medicine works by enabling your immune system to attack and destroy these abnormal white blood cancer cells.

2. What you need to know before you use BLINCYTO®

BLINCYTO® should not be administered to you:

- if you are hypersensitive (allergic) to blinatumomab or any of the other ingredients of

BLINCYTO® (listed in section 6).

- if you are breastfeeding.

Warnings and precautions

Tell your doctor or health care provider before being given the infusion: if you have ever had **neurological problems** (e.g., seizures, memory loss, confusion, disorientation, loss of balance, or difficulty in speaking)

- if you have an active infection
- if you have ever had an infusion reaction after previously using BLINCYTO®.

Tell your doctor or health care provider immediately if you experience any of the following reactions whilst receiving BLINCYTO® as these may need to be treated and your dose adjusted:

- if you experience seizures, difficulty in speaking or slurred speech, confusion and disorientation, or loss of balance.
- if you develop chills or shivering, or feel warm; you should take your temperature as you may have a fever - these may be symptoms of an infection.
- if you develop a reaction at any time during your infusion, which may include dizziness, face swelling, difficulty breathing, wheezing, or rash.
- if you have severe and persistent stomach pain, with or without nausea and vomiting, as these may be symptoms of a serious and potentially fatal condition known as pancreatitis (inflammation of the pancreas).

Your doctor or health care provider will monitor you for signs and symptoms of these reactions.

Other medicines and BLINCYTO®

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Tell your doctor or nurse if you think you may need any vaccinations in the near future, including those needed to travel to other countries. Some vaccines must not be given within 2 weeks before, at the same time as, or in the months after you receive treatment with BLINCYTO®. Your doctor will check if you should have the vaccination.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
Tell your doctor or health care provider if you became pregnant whilst receiving BLINCYTO®. Your doctor will talk to you about precautions in using vaccinations for your baby.

Pregnancy, breastfeeding and fertility.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Tell your doctor or nurse if you become pregnant during treatment with BLINCYTO®.
Your doctor may need to talk to you about precautions in using vaccinations for your baby.

Women who are able to become pregnant should use effective contraception during treatment and for at least 48 hours after treatment. Talk to your doctor or health care provider about suitable methods of contraception.

It is not known whether the ingredients in BLINCYTO® pass into breast milk. Tell your doctor or nurse if you are breastfeeding or are planning to breastfeed.
You should not breastfeed during treatment with BLINCYTO® and for at least 48 hours after your last treatment.

Driving and using machines
Do not drive, use heavy machines, or engage in hazardous activities while you are being given BLINCYTO®. BLINCYTO® can cause neurological problems such as dizziness, seizures, and confusion.

3. How to use BLINCYTO®
Do not share medicines prescribed for you with any other person.
Always use BLINCYTO® exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with BLINCYTO® will last. If you have the impression that the effect of BLINCYTO® is too strong or too weak, tell your doctor or pharmacist.

How BLINCYTO® is given

You will not be expected to give yourself BLINCYTO®. It will be given to you by a person who is qualified to do so. Follow your health care providers instructions when receiving BLINCYTO®. If you have any further questions regarding the infusion of BLINCYTO®, contact your health care provider.

BLINCYTO® will be given to you through a vein (intravenous) continuously for 4 weeks by an infusion pump, followed by a 2-week break during which you will not be given the infusion (this is 1 treatment cycle).
After this 2-week break, your doctor will determine if you will be given additional cycles.
The number of treatment cycles and the dose that you will be given will depend on how you tolerate and how you are responding to treatment with BLINCYTO®; your doctor will discuss with you how long you will be given BLINCYTO®.
Additionally, your treatment may be interrupted depending on how well you tolerate BLINCYTO®.
Detailed instructions for your doctor, nurse, and pharmacist on how to prepare and infuse BLINCYTO® are included in the prescribing information. Your doctor will determine when your BLINCYTO® infusion bag will be changed. The infusion rate may be faster or slower depending on how often the bag is changed.

<u>Treatment of Relapsed or Refractory B-cell precursor ALL</u>

It is recommended that the first 9 days of your first treatment cycle and the first 2 days of your second cycle with BLINCYTO® be given to you in a hospital or clinic under the supervision of a doctor or nurse experienced in the use of anti-cancer medicines.

Patients greater than or equal to 45 kg body weight

Your first cycle:
For the first week of BLINCYTO® treatment, your pump will be set to deliver a dose of 9 micrograms per day. Your dose of BLINCYTO® should be increased to 28 micrograms per day for weeks 2, 3, and 4 of your treatment depending on how you respond to treatment with BLINCYTO®.
Your next cycles:

If your doctor determines that more cycles of BLINCYTO® should be given, your pump will be set to deliver a dose of 28 micrograms per day.
You may not be able to tell the difference between the 9 micrograms per day and 28 micrograms per day infusion bags.

Patients less than 45 kg body weight

The dose that your pump will be set to deliver is based on your weight.
Your first cycle:
After the first week of BLINCYTO® treatment, the dose of BLINCYTO® should be increased for weeks 2, 3, and 4 of your first cycle depending on how you respond to treatment with BLINCYTO®.
Your next cycles:
Your doctor will determine if more cycles of BLINCYTO® should be given.
You may not be able to tell the difference between the dose delivered during the first week of your first cycle and the increased dose delivered for the remainder of the first cycle and for the subsequent cycles.

Maintenance therapy:

Your doctor may prescribe up to 4 treatment cycles of BLINCYTO® as maintenance therapy. BLINCYTO® will be given to you for 4 weeks, followed by an 8-week break during which you will not receive BLINCYTO®.

Treatment of MRD-positive B-cell Precursor ALL

It is recommended that the first 3 days of your first treatment cycle and the first 2 days of your second cycle with BLINCYTO® be given to you in a hospital or clinic under the supervision of a doctor or nurse experienced in the use of anticancer medicines.

Patients greater than or equal to 45 kg body weight

All treatment cycles:
Your doctor will determine the number of cycles of BLINCYTO® that should be given. Your pump will be set to deliver a dose of 28 micrograms per day.

Medicines given before each cycle of BLINCYTO®

Before your treatment with BLINCYTO®, you will be given other medicines (pre-medication) to help reduce infusion reactions and other possible side effects.
These may include corticosteroids (e.g., dexamethasone).

Infusion catheter

If you have a catheter for infusion, it is very important to keep the area around the catheter clean; otherwise you could get an infection. Your doctor or nurse will show you how to care for your catheter site.

Infusion pump and intravenous tubing

Do not adjust the settings on the pump, even if there is a problem or the pump alarm sounds. Any changes to the pump settings may results in a dose that is too high or too low.

Contact your doctor or nurse immediately if:

- there is a problem with the pump or the pump alarm sounds
- the infusion bag empties before the scheduled bag change
- if the infusion pump stops unexpectedly. Do not try to restart your pump.

Normal everyday activities will not affect how well the infusion pump and intravenous tubing work. Contact your health care provider if you have questions about your daily activities and pump function.

If you take more BLINCYTO® than you should

Since a health care provider will administer BLINCYTO®, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use BLINCYTO®

Since a health care provider will administer BLINCYTO®, it is unlikely that the dose will be missed.

4. Possible side effects

BLINCYTO® can have side effects.
Not all side effects reported for BLINCYTO® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BLINCYTO®, please consult your

health care provider for advice.

Side effects may include:

- infections in the blood, including bacteria, fungi, viruses, or infections in other organs *(bacterial infections, fungal infections, viral infections, other pathogen infections)*
- decreased levels of white blood cells with fever *(febrile neutropenia)*, decreased levels of red blood cells *(anaemia)*, decreased levels of white blood cells *(neutropenia, leukopenia, lymphopenia)*, decreased levels of platelets *(thrombocytopenia)*, increased levels of white blood cell count *(leucocytosis)*, swollen lymph nodes *(lymphadenopathy),* a life-threatening condition leading to inflammation due to build-up of certain white blood cells *(hemophagocytic histiocytosis)*
- fever, swelling, chills, decreased or increased blood pressure and fluid in the lungs, which may become severe *(cytokine release syndrome, cytokine storm)*, allergic reaction *(hypersensitivity)*
- complications during or after cancer treatment that may lead to increased blood levels of potassium, uric acid, and phosphorus and decreased blood levels of calcium *(tumour lysis syndrome)*
- not being able to sleep *(insomnia)*, confusion, disorientation
- headache, shaking *(or tremor)*, dizziness; drowsiness *(somnolence)*, disturbances of brain function *(encephalopathy)* such as speech disorder, difficulty in communicating *(aphasia)*, seizure, difficulty remembering *(memory impairment)*, difficulty thinking or processing thoughts *(cognitive disorder)*; tingling of skin *(paraesthesia)*, reduced pain or touch sensation *(hypoesthesia)*, nerve problems affecting the head and neck such as visual disturbances, difficulty with facial movements, difficulty hearing, and trouble swallowing *(cranial nerve disorders)*
- rapid heart rate *(tachycardia)*
- low blood pressure *(hypotension)*, high blood pressure *(hypertension),* flushing, a condition which causes fluid to leak from the small blood vessels into your body *(capillary leak syndrome)*
- dry or wet cough, shortness of breath *(dyspnoea)*
- rash
- back pain, pain in extremity, bone pain

- fever *(pyrexia)*, swelling of hands, ankles or feet *(peripheral oedema)*, chest pain, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing *(oedema)*
- increased weight, low blood levels of antibodies called “immunoglobulins” (IgG) which help the immune system against infection *(decreased immunoglobulins)*, increased levels of liver enzymes
- increases in other liver chemistry tests *(hyperbilirubinemia)*
- reactions related to infusion of the medicine such as face swelling, low blood pressure, and high blood pressure *(infusion-related reactions)*, overdose

Additionally, the side effects that happened more often in adolescents and children include:

- decreased levels of red blood cells *(anaemia)*, decreased levels of platelets *(thrombocytopenia)*, decreased levels of white blood cells *(leukopenia)*
- fever *(pyrexia)*
- reactions related to infusion of the medicine such as face swelling, low blood pressure, and high blood pressure *(infusion-related reaction)*
- increased weight
- high blood pressure *(hypertension)*

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BLINCYTO®.

Alternatively, you can report side effects to:

Amgen South Africa (Pty) Ltd.

Tel: +27 (0)11 100 5300

Email: safety-south-africa@amgen.com

5. How to store BLINCYTO®

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton.

Unopened vials:

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Store in the original carton in order to protect from light.

Reconstituted solution (BLINCYTO® solution):

When refrigerated (2 °C – 8 °C), the reconstituted solution must be used within 24 hours.

Alternatively, the vials can be stored at room temperature (23 °C to 27 °C) for up to 4 hours.

Diluted solution (prepared infusion bag):

If your infusion bag is changed at home:

- Infusion bags containing BLINCYTO® solution for infusion will arrive in special packaging containing cooling packs.
- Do not open the package.
- Store the package at room temperature (23 °C to 27 °C).
- Do not refrigerate or freeze the package.
- The package will be opened by your nurse and the infusion bags will be stored in a refrigerator until infusion.
- When refrigerated, the infusion bags must be used within 10 days of preparation.
- Once at room temperature (23 °C to 27 °C) the solution will be infused within 96 hours.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What BLINCYTO® contains

- The active ingredient in BLINCYTO® is blinatumomab.
- The other ingredients are citric acid monohydrate, trehalose dehydrate, lysine hydrochloride, polysorbate 80, and sodium hydroxide.

- IV Solution Stabilizer contains citric acid monohydrate, lysine hydrochloride, polysorbate 80, sodium hydroxide, and water for injection.

What BLINCYTO® looks like and contents of the pack

BLINCYTO® is a powder for concentrate and solution for solution for infusion.

Each pack of BLINCYTO® contains:

- 1 single-use BLINCYTO® vial containing a sterile, preservative free, white to off-white lyophilized powder in a vial (type I glass) with a grey stopper (elastomeric rubber), seal (aluminium), a yellow flip off cap and grey skirt (aluminium look) and
- 1 single-use IV Solution Stabilizer vial containing sterile, preservative free, colourless-to-slightly yellow, clear solution in a vial (type I glass) with a grey stopper (elastomeric rubber), seal (aluminium), a clear flip off cap and red skirt.

IV bags containing BLINCYTO® solution for infusion will be prepared by your doctor, nurse, or pharmacist.

Holder of Certificate of Registration

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