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Blincyto (*blinatumomab*)

An overview of Blincyto and why it is authorised in the EU

What is Blincyto and what is it used for?

Blincyto is a cancer medicine used to treat a type of blood cancer that affects B cells (a type of white blood cell) called B-precursor acute lymphoblastic leukaemia (ALL). It is used in adults whose cancer cells have a protein called CD19 on their surface (CD19-positive) and is:

- Philadelphia chromosome-positive (Ph-positive), which means that the cancer cells have an abnormal chromosome called the Philadelphia chromosome. Blincyto is used if the cancer has not responded to previous treatments with at least two medicines known as tyrosine kinase inhibitors and there are no other treatment options available;
- Philadelphia chromosome-negative (Ph-negative), where the cancer cells do not have an abnormal Philadelphia chromosome. Blincyto is used in adults who still have a small number of cancer cells remaining after previous treatment (referred to as minimal residual disease).

Blincyto is also used in adults with newly diagnosed Ph-negative ALL when the cancer cells have a protein called CD19 on their surface (CD19-positive). It is used as part of consolidation therapy (treatment to improve remission).

Blincyto is used in children aged 1 month and older with Ph-negative ALL, CD19-positive B-cell precursor ALL. It is used when the cancer:

- has not improved or has come back after two previous therapies or has come back following an allogenic haematopoietic stem cell transplantation (a procedure where the patient's bone marrow is replaced by stem cells from a donor to form new bone marrow that produces healthy cells);
- has come back for the first time and is considered high risk. Blincyto is used as part of consolidation therapy.

ALL is rare, and Blincyto was designated an 'orphan medicine' (a medicine used in rare diseases) on 24 July 2009. Further information on the orphan designation can be found here.

Blincyto contains the active substance blinatumomab.

How is Blincyto used?

Blincyto can only be obtained with a prescription, and treatment should be started by a doctor who has experience in the treatment of patients with blood cancer.

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Blincyto is given by infusion (drip) into a vein. The dose depends on the patient's bodyweight. Blincyto is infused continuously during a treatment cycle of four weeks. Each cycle is separated by a two-week treatment-free interval.

The number of cycles depends on the type of B-precursor ALL being treated and how the patient responds to treatment. Treatment may be interrupted or stopped altogether if the patient develops certain side effects.

Before receiving Blincyto, patients should be given medicines to prevent fever and reactions to the infusion. Patients should also be given chemotherapy medicines injected in the spine area to prevent leukaemia in the nervous system.

For more information about using Blincyto, see the package leaflet or contact your doctor or pharmacist.

How does Blincyto work?

In B-precursor ALL, certain cells form B cells that multiply too quickly. Eventually these abnormal blood cells replace the normal ones.

The active substance in Blincyto, blinatumomab, is an antibody that has been designed to attach to a protein (CD19) found on B cells, including ALL cells. It also attaches to a protein (CD3) on T cells (another type of white blood cell).

Blincyto therefore acts as a 'bridge', bringing T cells and B cells together and causing the T cells to release substances that kill the cancerous B cells.

What benefits of Blincyto have been shown in studies?

Blincyto has been studied in two main studies in adults with B-precursor ALL whose leukaemia had come back or had not improved with treatment. Patients were given Blincyto for up to five treatment cycles and Blincyto was not compared with any other treatment. The main measure of effectiveness was based on the percentage of patients whose ALL improved after two treatment cycles, measured as resolution of signs of leukaemia and a normalisation or improvement in blood cell counts.

The first study involved 189 patients with Ph-negative B-cell precursor ALL and found that it improved in 43% (81 out of 189) of patients given Blincyto. In most patients whose ALL improved, there was no evidence of cancer cells. Patients lived for an average of around six months before the cancer came back, which could enable suitable patients to have a stem cell transplant.

The second study was in patients with Ph-positive B-cell precursor ALL who were previously treated with at least two tyrosine kinase inhibitors. Results showed that for 36% (16 out of 45) of patients their ALL improved.

A third study involved adults, aged 30 years to 70 years of age, with newly diagnosed, Ph-negative, B-cell precursor ALL. The study found that patients given Blincyto as part of consolidation therapy lived longer than patients given consolidation therapy alone. After induction therapy (first treatment to kill as many cancer cells as possible) and intensification therapy (additional treatment if the cancer disappears following the first treatment), 286 patients who had no signs of cancer were given either Blincyto together with consolidation therapy or consolidation therapy alone. Around 82% of patients given Blincyto as part of consolidation therapy were alive after 5 years compared with around 63% of patients given consolidation chemotherapy alone.

A study in 70 children aged 1 year and above with Ph-negative B-precursor ALL found that, in 33% of patients, treatment with Blincyto led to a resolution of the disease.

Another study in 108 children above 28 days of age with relapsed high-risk Ph-negative B-precursor ALL found that, when Blincyto was used as part of the consolidation therapy, 33% of patients had events (such as relapse after responding to treatment or lack of response) compared with 57% of patients on standard consolidation chemotherapy.

Blincyto has also been studied in a main study in 116 patients with minimal residual disease. In the study, Blincyto was not compared with any other treatment. Results showed that around 78% of patients did not have detectable cancer cells after treatment with Blincyto.

In addition, data showed that when Blincyto is given to children aged 1 month to 1 year of age, blood levels of the medicine were similar to those seen in older children and adults. The company also provided data from the literature on the use of Blincyto in children aged from 1 month to less than 1 year of age with CD19 positive B-cell precursor ALL, which supported its use in these patients.

What are the risks associated with Blincyto?

For the full list of side effects and restrictions with Blincyto, see the package leaflet.

The most common side effects with Blincyto (which may affect more than 1 in 10 people) include infections, fever, infusion-related reactions (like fever, changes in blood pressure and rash), headache, febrile neutropenia (low levels of a type of white blood cells called neutrophils with fever), constipation, nausea (feeling sick), diarrhoea, vomiting, anaemia (low levels of red blood cells), oedema (swelling because of fluid retention), neutropenia (low levels of neutrophils), leucopenia (low levels of white blood cells), thrombocytopenia (low levels of blood platelets), blood tests showing changes in liver function, tremor (shaking), back pain, chills, low blood pressure, low levels of immunoglobulins (antibodies), cytokine release syndrome (a life-threatening condition that can cause fever, vomiting, shortness of breath, pain and low blood pressure), tachycardia (rapid heartbeat), insomnia (difficulty sleeping), pain in the arms and legs, abdominal (belly) pain, cough and rash.

The most serious side effects include infections, neutropenia with or without fever, neurological events (such as confusion, shaking, dizziness, numbness or tingling), cytokine release syndrome and tumour lysis syndrome (a life-threatening complication due to the breakdown of cancer cells).

Blincyto must not be given to women who are breastfeeding.

Why is Blincyto authorised in the EU?

The European Medicines Agency decided that Blincyto’s benefits are greater than its risks and it can be authorised for use in the EU. The Agency noted that Blincyto is beneficial for adults and children with high-risk Ph-negative B-precursor ALL who have few therapeutic options and who generally have a poor prognosis. It is also of benefit in adults with Ph-negative, CD19-positive B-cell precursor ALL who are at high risk of the cancer coming back when used as part of consolidation therapy. However, there are limited data on the benefits of Blincyto in patients with this form of B-precursor ALL who are under 30 years of age, including children, and who are at risk of the cancer coming back. Blincyto is also effective in adults who have Ph-positive B-precursor ALL that has not responded to previous treatment with medicines called tyrosine kinase inhibitors.

The safety profile of Blincyto was considered acceptable provided that recommendations on its use are followed.

Blincyto was originally given 'conditional authorisation'. The authorisation has now been switched to standard authorisation as the company has provided additional data requested by the Agency.

What measures are being taken to ensure the safe and effective use of Blincyto?

The company that markets Blincyto will provide data from two studies looking at the safety and use of Blincyto in clinical practice, including in children.

The company will also provide patients and healthcare professionals with educational materials on how Blincyto should be used and how to manage risks with the medicine. Patients will also be provided with an alert card.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Blincyto have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Blincyto are continuously monitored. Suspected side effects reported with Blincyto are carefully evaluated and any necessary action taken to protect patients.

Other information about Blincyto

Blincyto received a conditional marketing authorisation valid throughout the EU on 23 November 2015. This was switched to a full marketing authorisation on 18 June 2018.

Further information on Blincyto can be found on the Agency's website: ema.europa.eu/medicines/Human/EPAR/blincyto.

This overview was last updated in 01-2025.