BLINCYTO® ▼ (blinatumomab)

Important Risk Minimisation Information for Patients and Caregivers

The information in this guide is not intended to take the place of discussions with your doctor or other healthcare professionals.

For complete information on the side effects of BLINCYTO, patients should read the Package Leaflet. If you have any questions about BLINCYTO please speak to your doctors or nurses, or refer to the Package Leaflet, on the European Medicines Agency website under following link: https://www.ema.europa.eu/en/medicines/human/EPAR/blincyto#product-information-section To obtain additional copies of the Package Leaflet, please contact Cherubino Ltd, Delf Building, Sliema Road, Gzira or via email on pharmacovigilance@cherubino.com.mt

As part of the BLINCYTO Marketing Authorisation in EU, this guide has been developed for patients being treated with BLINCYTO or their caregivers, to provide further information about **how to minimise or prevent the Neurologic events including immune effector cell-associated neurotoxicity syndrome (ICANS) associated with the use of BLINCTYO**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get to the Malta Medicines Authority, Sir Temi Zammit Buildings, Malta Life Science Park, San Gwann SGN 300 Malta or at http:/www.medicinesauthority.gov.mt/adrportal. Adverse reactions should also be reported to Cherubino Ltd on 21343270 or pharmacovigilance@cherubino.com.mt

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1 Overview of BLINCYTO Treatment

What is BLINCYTO?

- BLINCYTO is a medicine that works by enabling your immune system to attack and destroy the abnormal white blood cancer cells.

What is BLINCYTO used for?

- BLINCYTO is a treatment for B-precursor acute lymphoblastic leukaemia (ALL).
- B-precursor acute lymphoblastic leukaemia (ALL) is a cancer of the bone marrow and blood in which a particular kind of white blood cell called “B-lymphocyte” is growing out of control.

How is BLINCYTO given?

- Blincyto is given as continuous intravenous infusion:
    - BLINCYTO is delivered through a vein (intravenously) continuously using an infusion pump.
    - An infusion catheter will be attached to you at all times during each cycle of your treatment.
- Your doctor will discuss with you the duration of your hospitalisation and the number and length of cycles required for your BLINCYTO treatment.
- Your doctor will determine when your BLINCYTO infusion bag will be changed, which may range from every day to every 4 days.

2 Important Things For You And Your Caregiver To Know About Neurologic Events Including ICANS Whilst Using BLINCYTO

- BLINCYTO may cause neurologic events. The key signs and symptoms of these events are:
    - uncontrolled shaking (or tremor)
    - confusion
    - disturbances of brain function (encephalopathy)
    - difficulty in communicating (aphasia) and/or writing (dysgraphia)
    - seizure (convulsion)
- Some of these events may be signs of a serious immune reaction called ‘immune effector cell-associated neurotoxicity’ (ICANS). Please seek **urgent** attention from your doctor or nurse immediately if you experience any of the symptoms listed above.
- Please do not drive or operate moving vehicles/heavy machinery or engage in hazardous activities whilst receiving BLINCYTO.

Please report any side effects you may experience. Refer to page 1 of this guide for details on how to report.

[This Guide for Patients and Caregivers fulfills the conditions of the marketing authorization and has been approved by the competent authority.]