BLINCYTO®, blinatumomab

Update for the Additional Risk Minimisation Measures - Educational Packages for Blincyto

09.01.2019

Dear Healthcare Professional,

Cherubino Ltd in collaboration with Amgen, in agreement with the European Medicines Agency (EMA) and Malta Medicines Authority would like to inform you of the following:

Summary

The approved indication for Blincyto has recently been updated and now includes:

- Use as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL).

- Use as monotherapy for the treatment of paediatric patients aged 1 year or older with Philadelphia chromosome negative CD19 positive B-cell precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.

Background on the safety concern

Amgen would like to provide you with the updated Educational Packages as part of the additional Risk Minimisation Measures implemented in agreement with the European Medicines Agency (EMA) and Malta Medicines Authority. As part of the initial marketing authorisation for Blincyto, these materials were developed to communicate the risk of neurologic events and possible risk associated with medication errors, including overdose to healthcare providers and patients. They have now been updated to also reflect the necessary precautions to minimise the risks associated with the Blinatumomab treatment for paediatric patients.

You are being provided with the following materials:

- Physician educational material Version 2.0
- Pharmacist educational material Version 3.0
- Nurse educational material Version 2.0
- Patient / caregivers educational material Version 2.0
- Patient alert card Version 1.0

These materials contain important information regarding prescribing, preparation, and administration of blinatumomab, the risks associated with use of blinatumomab and the necessary precautions to minimise the risks.

Please read the updated physician educational material carefully and provide pharmacist and nurses supporting you in your treatment of adult and paediatric ALL patients with Blinatumomab with the respective educational brochures for their roles.

Please make sure you walk your patient through the patient/caregiver material and the package leaflet so that the patients/caregivers understand the risks as well as the recommended mitigation actions.

Make sure you provide each patient with a patient alert card completed with the respective contact details for use in emergency situations.

Call for reporting
Please report any adverse reactions to the Medicines Authority by post or e-mail: ADR reporting/ Sir Temi Zammit Building, Malta Life Sciences Park, San Gwann or on www.medicinesauthority.gov.mt/adrportal

▼ Blincyto is subject to additional monitoring. This will allow quick identification of new safety information.

Contact details

Should you have any questions or require additional information regarding the use of the Blincyto additional risk minimization material please contact Medical Information on Cherubino Ltd, Delf Building, Sliema Road, Gzira, GZR 1637. Telephone number 21 343270 and email: pharmacovigilance@cherubino.com.mt for access to further information

Additional copies of the educational brochures and/or patient cards can be requested by contacting Cherubino Ltd Medical Representative Elaine Spiteri on 21343270.

Sincerely

Annex

Educational Brochure for Physicians Version 2.0
Educational Brochure for Pharmacist Version 3.0
Educational Brochure for Nurses Version 2.0
Educational Brochure for Patients/Caregivers Version 2.0
Patient Alert Card Version 1.0