Cherubino Ltd.
Since 1906
YOUR HEALTH AT HEART

30.08.2019

BLINCYTO® (blinatumomab) – Clarification of premedication with dexamethasone in paediatric patients

Dear Healthcare Professional,

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

Summary

- A potentially confusing statement which led to a translation issue has been discovered in the Blincyto Summary of Product Characteristic (SmPC) Section 4.2 regarding the second administration of dexamethasone as premedication in paediatric patients.

- The subsection 'Premedication and additional medication recommendations' states:

  In paediatric patients, dexamethasone 10 mg/m² (not to exceed 20 mg) should be administered orally or intravenously 6 to 12 hours prior to the start of BLINCYTO (cycle 1, day 1). This should be followed by dexamethasone 5 mg/m² orally or intravenously ***within 30 minutes of the start of BLINCYTO*** *(cycle 1, day 1).*

- The correct meaning is:

  In paediatric patients, dexamethasone 10 mg/m² (not to exceed 20 mg) should be administered orally or intravenously 6 to 12 hours prior to the start of BLINCYTO (cycle 1, day 1). This should be followed by dexamethasone 5 mg/m² orally or intravenously ***within 30 minutes PRIOR TO the start of BLINCYTO*** *(cycle 1, day 1).*

- The Physician Education Brochure is also affected by the above translation issue. The remaining educational materials (for pharmacists, nurses and patient/caregivers) are not affected and therefore do not require any update.
- The translation issue only affects paediatric patients; the instructions for adult patients are correct.
- Dexamethasone is administered to patients prior to receiving Blincyto in order to prevent or reduce the severity of cytokine release syndrome (CRS), a potentially life-threatening or fatal adverse reaction, which has been observed in patients who have received Blincyto for the treatment of ALL. It is therefore important that patients receive appropriate dexamethasone prophylaxis prior to the initiation of Blincyto infusion.
- The updated English Blincyto SmPC and impacted translations are currently under review by the European Medicines Agency (EMA), therefore the final wording in the SmPC may still change. The Physician Education Brochure has been updated in alignment with the proposed SmPC.
- Please share this information with personnel concerned.

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. The PEB has now been updated to clarify and edit the potentially confusing statement which led to a translation issue that has been discovered in the Blincyto Summary of Product Characteristic (SmPC) Section 4.2 regarding the second administration of dexamethasone as premedication in paediatric patients.

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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.

Company contact point

Should you have any questions or require additional information regarding the use of Blincyto, please contact Amgen's local representative Cherubino Ltd, Delf Building, Sliema Road, Gzira, GZR 1637. Telephone number 21 343270 and email: pharmacovigilance@cherubino.com.mt for access to further information

Yours Sincerely,

Annalisa Francalanza
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Cherubino Ltd