AMGEN Ireland Limited
21 Northwood Court
Santry
Dublin
D09 TX31
Tel: 00353 1 8527400
Fax: 00353 1 8527499

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

Dear Healthcare Professional,

Amgen 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/m^2 (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/m^2 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/m^2 (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/m^2 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.

Summary of Recommendations for Health Care Professionals
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 other members of the treatment team.

This letter is being sent in agreement with the Health Products Regulatory Authority (HPRA) and European Medicines Agency.

Call for reporting

▼ This medicinal product is subject to additional monitoring.
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort terrace, IRL-Dublin 2; Tel: +353 1 676 49 71; Fax: +353 1 676 25 17. Website: www.hpra.ie; Email: medsafety@hpra.ie. Adverse events should also be reported to Amgen Limited on 1800 535160

Reports can also be made to Amgen Europe B.V. by contacting Amgen UK/Ireland Medical Information on 1800 535160.

Contact details

For additional copies of any of the updated Blincyto® risk minimisation materials, or the educational brochures for nurses or for pharmacists, and for any queries or additional information regarding Blincyto®, please contact Amgen UK/Ireland Medical Information on 1800 535160 or by email to gbinfoline@amgen.com.

Prescribing information for Blincyto®can be accessed at http://www.medicines.ie/.

Prescribing information and electronic copies of the risk minimisation materials for Blincyto® can also be accessed on the HPRA website at https://www.hpra.ie/.

Yours sincerely,

Dr Anthony Patrikios
Executive Medical Director, UK & Ireland
MBBCh MRCGP FFPM MBA

Enc:
1x Physician Education Brochure Version 4.0