

**From:** Amgen Inc.  
**To:** <Professional Society email>  
**Subject:** FDA-Required Updated REMS Safety Information for BLINCYTO®



## FDA-REQUIRED UPDATED REMS SAFETY INFORMATION

### BLINCYTO® (blinatumomab) REMS

**Risk of:**

- Cytokine Release Syndrome (CRS), which may be life-threatening or fatal
- Neurological Toxicities, which may be severe, life-threatening or fatal
- Preparation and Administration Errors

April 2020

Dear [name]:

The Food and Drug Administration (FDA) has required this safety notice as part of the BLINCYTO® REMS (Risk Evaluation and Mitigation Strategy) to be distributed to the [insert Professional Society Name] to highlight new safety information about **cytokine release syndrome and neurological toxicities**. Amgen requests that you distribute the information to your members, informing them about the serious risks of BLINCYTO.

#### BOXED WARNING: Cytokine Release Syndrome

- CRS, which may be life-threatening or fatal, occurred in patients receiving BLINCYTO.
- Monitor patients for signs or symptoms of CRS.
- BLINCYTO has been recently approved for the treatment of minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

New

- In patients treated for MRD-positive B-cell precursor ALL, hospitalization is recommended for the first 3 days of the first cycle and the first 2 days of the second cycle.
- In patients treated for relapsed or refractory B-cell precursor ALL, hospitalization is recommended for the first 9 days of the first cycle and the first 2 days of the second cycle.

New

- Administer corticosteroids for severe or life-threatening CRS.

#### BOXED WARNING: Neurological Toxicities

- In patients with ALL receiving BLINCYTO in clinical studies, neurological toxicities have occurred in approximately 65% of patients.

New

- Manifestations of neurological toxicity included cranial nerve disorders.

#### OTHER SERIOUS RISKS: Preparation and Administration Errors

- It is very important that the instructions for preparation (including admixing) and administration are strictly followed to minimize medication errors (including underdose and overdose).

Please see the non-promotional [REMS Fact Sheet](#), reviewed by the FDA, and the full Prescribing Information for more detailed safety information. Additional copies of the Fact Sheet and other important information are available at: [www.blinicytorems.com](http://www.blinicytorems.com).

BLINCYTO is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of adults and children with 1) B-cell precursor ALL in first or second complete remission with MRD greater than or equal to 0.1% and 2) relapsed or refractory B-cell precursor ALL.

Sincerely,

Lisa L. Bollinger, MD  
Vice President, Global Patient Safety, Labeling and Pediatric Regulatory

## BLINCYTO<sup>®</sup> (blinatumomab) REMS

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