

From: Amgen Inc.  
To: <Healthcare Provider 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

Month 2021

Dear Healthcare Provider:

The Food and Drug Administration (FDA) has required this safety notice as part of the BLINCYTO® REMS (Risk Evaluation and Mitigation Strategy) to highlight risk information about cytokine release syndrome and neurological toxicities for BLINCYTO. In addition, Amgen would like to highlight updated preparation and administration instructions.

Please see the non-promotional [REMS Fact Sheet](#) for more detailed safety information.

### **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 is approved for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children and for the treatment of relapsed or refractory CD19-positive B-cell precursor ALL in adults and children.
  - In patients treated for CD19-positive B-cell precursor ALL in first or second complete remission with MRD, 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 CD19-positive 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.
- 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.
- Manifestations of neurological toxicity included cranial nerve disorders.

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

-  Please refer to the updated instructions on the preparation and administration of BLINCYTO in Sections 2.5 and 2.6 of the Prescribing Information. It is very important that the instructions for preparation (including admixing) and administration are strictly followed to minimize medication errors (including underdose or 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.blincytoREMS.com](http://www.blincytoREMS.com).

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

To review the Prescribing Information and Medication Guide, see links below:

[Prescribing Information](#)

[Medication Guide](#)

### **REPORTING ADVERSE EVENTS**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. Healthcare Providers should report all suspected adverse events associated with BLINCYTO to the FDA or to Amgen at 1-800-77-AMGEN (1-800-772-6436).

Sincerely,

Fatima Bhayat MD MPH PhD FFPM  
Vice President, Global Patient Safety

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