

From: Amgen Inc.
To: <Pharmacist Email>
Subject: FDA-Required Updated REMS Safety Information for BLINCYTO®



**FDA-REQUIRED UPDATED
REMS SAFETY INFORMATION**

BLINCYTO® (blinatumomab) REMS

Risk of:

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

Month 2021

Dear Pharmacist:

The Food and Drug Administration (FDA) has required this safety notice as part of the BLINCYTO® REMS (Risk Evaluation and Mitigation Strategy) to remind you of the serious risk of preparation and administration errors and 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.

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 note that the recommended dose for BLINCYTO is by patient weight. Patients greater than or equal to 45 kg receive a fixed-dose. For patients less than 45 kg, the dose is calculated using the patient's body surface area (BSA).

Special Considerations to Support Accurate Preparation

- Intravenous (IV) Solution Stabilizer is provided and is used to coat the IV bag prior to addition of reconstituted BLINCYTO.
- Reconstitute BLINCYTO with preservative-free Sterile Water for Injection, USP, only.
- Aseptic technique must be done in a USP <797> compliant facility and strictly observed when preparing the solution for infusion since BLINCYTO does not contain antimicrobial preservatives.
- Use the specific volumes described in the admixing instructions.
- Please see the full Prescribing Information for important details on preparation and administration, including storage requirements for 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 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.

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.

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 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

BLINCYTO[®] (blinatumomab) REMS

Risk of:

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

Month 2021

Dear Pharmacist:

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

Preparation and Administration Errors

Note

- **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).
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