

BLINCYTO[®] (blinatumomab) REMS

FDA-REQUIRED UPDATED REMS SAFETY INFORMATION

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

March 2018

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 new risk information about cytokine release syndrome and neurological toxicities for BLINCYTO.

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 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 prefilled IV bag prior to addition of reconstituted BLINCYTO.
- Reconstitute BLINCYTO with 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

- 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.
 - 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.

New 

- 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.

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.

New

Please see the enclosed 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.blincytoems.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.

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,



Isma Benattia, MD, MBE
Vice President, Global Patient Safety & Labeling