



BLINCYTO® PRODUCT FACT SHEET

INDICATION

BLINCYTO® is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

PRODUCT INFORMATION

NDC	Description	Quantity
55513-160-01	 <p>1 BLINCYTO® 35 mcg single-dose vial containing a sterile, preservative-free, white to off-white lyophilized powder</p> <p>1 Intravenous Solution Stabilizer (IVSS) 10 mL single-dose glass vial containing a sterile, preservative-free, colorless to slightly yellow, clear solution</p>	1 BLINCYTO® vial and 1 IVSS vial per package

STORAGE AND HANDLING REQUIREMENTS

Store BLINCYTO® and IV Solution Stabilizer vials in the original package refrigerated at 2°C to 8°C (36°F to 46°F) and protect from light until time of use. Do not freeze. Store and transport the prepared IV bag containing BLINCYTO® solution for infusion at 2°C to 8°C (36°F to 46°F) conditions. Ship in packaging that has been validated to maintain temperature of the contents at 2°C to 8°C (36°F to 46°F). Do not freeze.

SHIPPING CONTAINER INFORMATION

BLINCYTO® and IVSS should be unpacked and refrigerated; they should not be stored in the shipping container. The prepared IV bags can be transported in packaging that has been validated to maintain temperature of the contents at 2°C to 8°C (36°F to 46°F).

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

ORDERING

Distributor	Item Number	Distributor	Item Number
ASD Healthcare	44076	McKesson Specialty Health	5004950
Cardinal Health Specialty Distribution	5046404	Oncology Supply	44076
McKesson Plasma & Biologics	5004950		

SUPPLIED AND MARKETED BY

Amgen USA Inc.
1-800-28-AMGEN (1-800-282-6436)
Fax: 1-800-29-AMGEN (1-800-292-6436)
www.amgen.com www.blinicyto.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact 1-877-669-9121. Credit for returns is subject to Amgen's Returned Goods Policy.

PRODUCT INFORMATION

Medical Information: 1-877-669-9121

REIMBURSEMENT INFORMATION

Amgen Assist 360™: 1-888-4ASSIST (1-888-427-7478)

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES

- Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® as recommended.
- Neurological toxicities, which may be severe, life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® as recommended.

Contraindications

BLINCYTO® is contraindicated in patients with a known hypersensitivity to blinatumomab or to any component of the product formulation.

Please see Important Safety Information on page 2.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- Cytokine Release Syndrome (CRS): CRS, which may be life-threatening or fatal, occurred in patients receiving BLINCYTO[®]. Infusion reactions have occurred and may be clinically indistinguishable from manifestations of CRS. Closely monitor patients for signs and symptoms of serious adverse events such as pyrexia, headache, nausea, asthenia, hypotension, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), and increased total bilirubin (TBIL). In some cases, disseminated intravascular coagulation (DIC), capillary leak syndrome (CLS), and hemophagocytic histiocytosis/macrophage activation syndrome (MAS) have been reported in the setting of CRS. Interrupt or discontinue BLINCYTO[®] as outlined in the Prescribing Information (PI).
- Neurological Toxicities: Approximately 65% of patients receiving BLINCYTO[®] in clinical trials experienced neurological toxicities. The median time to the first event was within the first 2 weeks of BLINCYTO[®] treatment and the majority of events resolved. The most common ($\geq 10\%$) manifestations of neurological toxicity were headache and tremor. Severe, life-threatening, or fatal neurological toxicities occurred in approximately 13% of patients, including encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. Monitor patients for signs or symptoms and interrupt or discontinue BLINCYTO[®] as outlined in the PI.
- Infections: Approximately 25% of patients receiving BLINCYTO[®] in clinical trials experienced serious infections such as sepsis, pneumonia, bacteremia, opportunistic infections, and catheter-site infections, some of which were life-threatening or fatal. Administer prophylactic antibiotics and employ surveillance testing as appropriate during treatment. Monitor patients for signs or symptoms of infection and treat appropriately, including interruption or discontinuation of BLINCYTO[®] as needed.
- Tumor Lysis Syndrome (TLS), which may be life-threatening or fatal, has been observed. Preventive measures, including pretreatment nontoxic cytoreduction and on-treatment hydration, should be used during BLINCYTO[®] treatment. Monitor patients for signs and symptoms of TLS and interrupt or discontinue BLINCYTO[®] as needed to manage these events.
- Neutropenia and Febrile Neutropenia, including life-threatening cases, have been observed. Monitor appropriate laboratory parameters (including, but not limited to, white blood cell count and absolute neutrophil count) during BLINCYTO[®] infusion and interrupt BLINCYTO[®] if prolonged neutropenia occurs.
- Effects on Ability to Drive and Use Machines: Due to the possibility of neurological events, including seizures, patients receiving BLINCYTO[®] are at risk for loss of consciousness, and should be advised against driving and engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery while BLINCYTO[®] is being administered.
- Elevated Liver Enzymes: Transient elevations in liver enzymes have been associated with BLINCYTO[®] treatment with a median time to onset of 3 days. In patients receiving BLINCYTO[®], although the majority of these events were observed in the setting of CRS, some cases of elevated liver enzymes were observed outside the setting of CRS, with a median time to onset of 19 days. Grade 3 or greater elevations in liver enzymes occurred in approximately 7% of patients outside the setting of CRS and resulted in treatment discontinuation in less than 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase (GGT), and TBIL prior to the start of and during BLINCYTO[®] treatment. BLINCYTO[®] treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if TBIL rises to > 3 times ULN.
- Pancreatitis: Fatal pancreatitis has been reported in patients receiving BLINCYTO[®] in combination with dexamethasone in clinical trials and the post-marketing setting. Evaluate patients who develop signs and symptoms of pancreatitis and interrupt or discontinue BLINCYTO[®] and dexamethasone as needed.
- Leukoencephalopathy: Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO[®], especially in patients previously treated with cranial irradiation and antileukemic chemotherapy.
- Preparation and administration errors have occurred with BLINCYTO[®] treatment. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).
- Immunization: Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of BLINCYTO[®] treatment, during treatment, and until immune recovery following last cycle of BLINCYTO[®].
- Risk of Serious Adverse Reactions in Pediatric Patients due to Benzyl Alcohol Preservative: Serious and fatal adverse reactions including "gasping syndrome," which is characterized by central nervous system depression, metabolic acidosis, and gasping respirations, can occur in neonates and infants treated with benzyl alcohol-preserved drugs including BLINCYTO[®] (with preservative). When prescribing BLINCYTO[®] (with preservative) for pediatric patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO[®] (with preservative) and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known. Due to the addition of bacteriostatic saline, 7-day bags of BLINCYTO[®] solution for infusion with preservative contain benzyl alcohol and are not recommended for use in any patients weighing < 22 kg.

Adverse Reactions

- The most common adverse reactions ($\geq 20\%$) in clinical trial experience of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL (TOWER Study) treated with BLINCYTO[®] were infections (bacterial and pathogen unspecified), pyrexia, headache, infusion-related reactions, anemia, febrile neutropenia, thrombocytopenia, and neutropenia. Serious adverse reactions were reported in 62% of patients. The most common serious adverse reactions ($\geq 2\%$) included febrile neutropenia, pyrexia, sepsis, pneumonia, overdose, septic shock, CRS, bacterial sepsis, device related infection, and bacteremia.
- Adverse reactions that were observed more frequently ($\geq 10\%$) in the pediatric population compared to the adult population were pyrexia (80% vs. 61%), hypertension (26% vs. 8%), anemia (41% vs. 24%), infusion-related reaction (49% vs. 34%), thrombocytopenia (34% vs. 21%), leukopenia (24% vs. 11%), and weight increased (17% vs. 6%).
- In pediatric patients less than 2 years old (infants), the incidence of neurologic toxicities was not significantly different than for the other age groups, but its manifestations were different; the only event terms reported were agitation, headache, insomnia, somnolence, and irritability. Infants also had an increased incidence of hypokalemia (50%) compared to other pediatric age cohorts (15-20%) or adults (17%).

Dosage and Administration Guidelines

- BLINCYTO[®] is administered as a continuous intravenous infusion at a constant flow rate using an infusion pump which should be programmable, lockable, non-elastomeric, and have an alarm.
- It is very important that the instructions for preparation (including admixing) and administration provided in the full Prescribing Information are strictly followed to minimize medication errors (including underdose and overdose).

Reference: BLINCYTO[®] (blinatumomab) prescribing information, Amgen, v5.

Please [click here](#) to see full Prescribing Information, including Boxed WARNINGS and Medication Guide, for BLINCYTO[®].