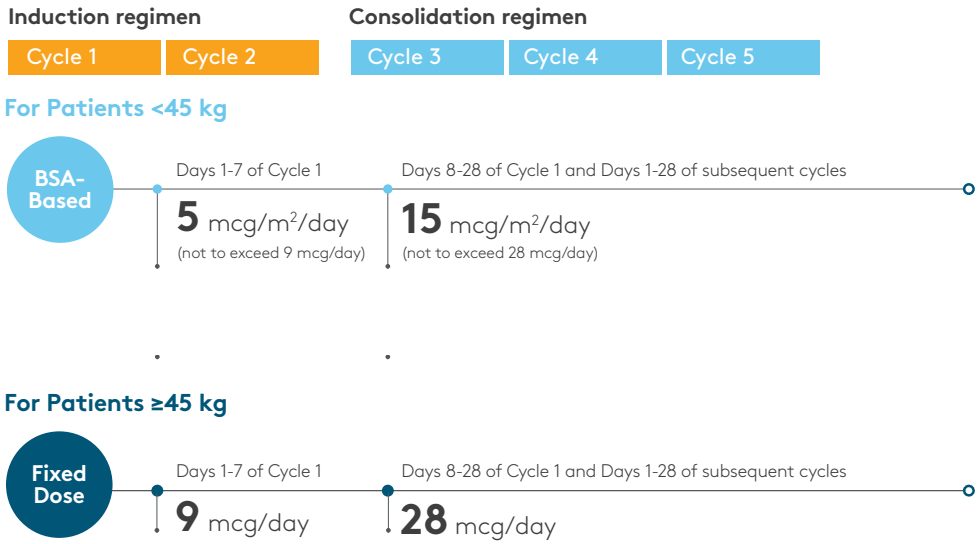
DOSAGE AND ADMINISTRATION

DOSING AND PREMEDICATION IN PATIENTS WITH RELAPSED OR REFRACTORY B-ALL[1]

TREATMENT CYCLES

- A single cycle of treatment consists of 4 weeks of continuous IV infusion followed by a 2-week treatment-free interval
- A treatment course consists of up to 2 induction cycles of BLINCYTO®, followed by up to 3 consolidation cycles



It is important to initiate treatment at the recommended starting dose in order to mitigate the risk of CRS.

PREMEDICATION

Intrathecal chemotherapy prophylaxis is recommended before and during BLINCYTO® therapy to prevent CNS ALL relapse.

Adult relapsed or refractory B-ALL patients should be premedicated with 20 mg IV dexamethasone 1 hour prior to initiation of each cycle to help minimise infusion reactions.

Paediatric relapsed or refractory B-ALL patients should be premedicated with dexamethasone 10 mg/m² (not to exceed 20 mg) orally or intravenously 6–12 hours prior to the start of BLINCYTO® (cycle 1 day 1), followed by premedication with dexamethasone 5 mg/m² orally or intravenously within 30 minutes of the start of BLINCYTO® (cycle 1 day 1).

PRE-PHASE TREATMENT FOR PATIENTS WITH HIGH TUMOUR BURDEN

For patients with ≥50% leukaemic blasts or >15,000/mcL peripheral blood leukaemic blast counts treat with dexamethasone (not to exceed 24 mg/day).

HOSPITALISATION

- Hospitalisation is recommended at a minimum for the first 9 days of the first treatment cycle and the first 2 days of the second cycle
- For all subsequent cycle starts and reinitiation (e.g. if treatment is interrupted for ≥4 hours), supervision by a healthcare professional or hospitalisation is recommended

Reference: 1. BLINCYTO® (blinatumomab) Product Information. www.amgen.com.au/Blincyto.PI.

DOSAGE AND ADMINISTRATION

VOLUME CALCULATIONS IN PATIENTS WITH RELAPSED OR REFRACTORY B-ALL WEIGHING ≥45 KG[1]

IV BAGS

Infusion time (rate)	24 hours (10 mL/h)		48 hours (5 mL/h)		72 hours (3.3 mL/h)		96 hours (2.5 mL/h)	
Dose (per day)	9 mcg	28 mcg	9 mcg	28 mcg	9 mcg	28 mcg	9 mcg	28 mcg
Number of reconstituted BLINCYTO® vials needed								
Volume of reconstituted BLINCYTO® required	0.83 mL	2.6 mL	1.7 mL	5.2 mL	2.5 mL	8 mL	3.3 mL	10.7 mL

250 ML CASSETTES

Cassette duration	24 hours		48 hours		72 hours		96 hours	
Dose (per day)	9 mcg	28 mcg	9 mcg	28 mcg	9 mcg	28 mcg	9 mcg	28 mcg
Number of reconstituted BLINCYTO® vials needed								
Volume of reconstituted BLINCYTO® required	0.75 mL	2.3 mL	1.5 mL	4.7 mL	2.25 mL	7 mL	3 mL	9.3 mL

Reference: 1. BLINCYTO® (blinatumomab) Product Information. www.amgen.com.au/Blincyto.PI.

DOSAGE AND ADMINISTRATION

VOLUME CALCULATIONS IN PATIENTS WITH RELAPSED OR REFRACTORY B-ALL WEIGHING <45 KG[1]

IV BAGS

Infusion time (rate)	24 hours (10 mL/hour)		48 hours (5 mL/hour)		72 hours (3.3 mL/hour)		96 hours (2.5 mL/hour)	
Dose (per day)	5 mcg/m²	15 mcg/m²	5 mcg/m²	15 mcg/m²	5 mcg/m²	15 mcg/m²	5 mcg/m²	15 mcg/m²
Number of reconstituted BLINCYTO® vials needed				 to		 to		 to
Volume of reconstituted BLINCYTO® required for BSA 0.4–1.59 m²†	0.2–0.7 mL	0.6–2.1 mL	0.4–1.4 mL	1.2–4.2 mL	0.6–2.1 mL	1.8–6.3 mL	0.8–2.8 mL	2.4–8.3 mL

250 ML CASSETTES

Cassette duration	24 hours		48 hours		72 hours		96 hours	
Dose (per day)	5 mcg/m²	15 mcg/m²	5 mcg/m²	15 mcg/m²	5 mcg/m²	15 mcg/m²	5 mcg/m²	15 mcg/m²
Number of reconstituted BLINCYTO® vials needed				 to		 to		 to
Volume of reconstituted BLINCYTO® required for BSA 0.4–1.59 m²†	0.19–0.65 mL	0.56–1.9 mL	0.37–1.3 mL	1.1–3.9 mL	0.56–1.9 mL	1.7–5.8 mL	0.74–2.6 mL	2.2–7.7 mL

BSA: body surface area. †See Product Information for exact dose of reconstituted BLINCYTO®.

Reference: 1. BLINCYTO® (blinatumomab) Product Information. www.amgen.com.au/Blincyto.PI.

BLINCYTO®
(blinatumomab)

For more information on BLINCYTO® or to report any adverse events or product complaints involving BLINCYTO® please contact Australia Medical Information on 1800 803 638

PBS Information: Section 100 listed. Authority required.
Refer to PBS Schedule for full Authority listing.

***WARNING*:** *The following have occurred in patients receiving BLINCYTO®:*
• Cytokine Release Syndrome, which may be life-threatening or fatal • Neurological toxicities, which may be severe, life-threatening, or fatal • Reactivation of JC viral infection
Interrupt or discontinue BLINCYTO® as recommended if any of these adverse events occur
(See Section 4.4 Special warnings and precautions for use and Section 4.2 Dose and method of administration).

REFER TO FULL PRODUCT INFORMATION BEFORE PRESCRIBING; AVAILABLE FROM AMGEN AUSTRALIA PTY LTD, PH: 1800 803 638 OR AT WWW.AMGEN.COM.AU/BLINCYTO.PI

For more information about BLINCYTO® or to report an adverse event or product complaints about BLINCYTO®, please contact Amgen Medical Information on 1800 803 638.

BLINCYTO® Minimum Product Information: Indication: treatment of relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukaemia (ALL); treatment of minimal residual disease (MRD) positive ALL in patients in complete haematological remission. **Contraindications:** hypersensitivity to blinatumomab, CHO-derived proteins or any excipient. **Precautions:** neurologic events; increased risk for serious infections; cytokine release syndrome; infusion reactions; tumour lysis syndrome, pancreatitis. Management of these adverse reactions may require interruption or discontinuation of treatment. Neutropenia and febrile neutropenia; elevated liver enzymes; leukoencephalopathy; medication errors – strictly follow preparation and administration instructions. Pregnancy Category: C. Use contraception during and for 48 hours after treatment. Discontinue breast-feeding during and for at least 48 hours after treatment. Do not use recommended adult fixed dose in paediatric patients. No data in patients aged less than 28 days. **Interactions:** low potential of clinically meaningful drug interaction with BLINCYTO® mediated cytokine elevation. Vaccination with live viral vaccines not recommended 2 weeks prior to or during treatment, and until recovery of B lymphocytes to normal range following last treatment cycle. **Adverse Reactions:** Common: infections, pyrexia, infusion-related reactions, headache, anaemia, febrile neutropenia, neutropenia, thrombocytopenia, oedema, increased liver enzymes, fatigue, nausea, tremor, hypokalaemia, diarrhoea, chills. See also Precautions for serious adverse reactions. **Dosage & Administration:** R/R ALL: Single cycle is 4 weeks continuous intravenous (cIV) infusion then 2 week treatment free interval. *For patients greater than or equal to 45 kg (fixed dose)*: Cycle 1 – starting dose 9 micrograms/day for days 1-7, then 28 micrograms/day for days 8-28. All other cycles 28 micrograms/day for 4 weeks. For patients less than 45 kg (body surface area based dose): Cycle 1 – starting dose 5 micrograms/m^2/day for days 1-7 (do not exceed 9 micrograms/day), then 15 micrograms/m^2/day (do not exceed 28 micrograms/day); all other cycles, 15 micrograms/m^2/day (do not exceed 28 micrograms/day). For maintenance, 28 day cIV infusion, then 56 days treatment free. Hospitalise at least first 9 days of Cycle 1 and first 2 days of Cycle 2. Supervision or hospitalisation for other cycle starts and reinitiation. Adults: premedicate with 20 mg IV dexamethasone prior to initiation of each cycle. Intrathecal chemotherapy prophylaxis recommended before and during therapy. Treat with dexamethasone (≤ 24 mg/day) if high tumour burden. Paediatrics: premedicate with dexamethasone 10 mg/m2 (not to exceed 20 mg) oral or IV 6 to 12 hours prior to start of BLINCYTO® (Cycle 1 day 1), followed by premedication with dexamethasone 5 mg/m^2 oral or IV within 30 minutes of start of BLINCYTO® (Cycle 1 day 1). **MRD+ ALL:** 28 day cIV infusion then 14 days treatment free, for up to 4 cycles; premedicate with prednisone 100 mg IV or equivalent 1 hour prior to start of BLINCYTO® each cycle; hospitalise first 3 days Cycle 1 and first 2 days Cycle 2, supervise/hospital for subsequent cycle starts and reinitiation – see full PI. R/R & MRD+ ALL – Interrupt BLINCYTO® if grade 3 neurological events, Cytokine Release Syndrome or other clinically relevant adverse reactions occur see full PI.

BLINCYTO®
(blinatumomab)

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