PURCHASING PROCEDURE

BLINCYTO® vials MUST be purchased direct from Amgen via the DHL Customer Service Team using a dedicated account set up solely for this purpose. Only BLINCYTO® can be purchased via this account; the specific account number for your institution will be advised in writing by separate communication.

A purchase order can be placed with the DHL Customer Service Team via the following methods:

t. 1800 077 421, Option 1

f. 1800 358 199

e. d2mcs@dhl.com

Your order should include the following details:

1. Your individual BLINCYTO® account number
2. The BLINCYTO® Product Code: 9003593
3. The quantity of BLINCYTO® 38.5mcg vials required

Importantly, delivery lead-times are influenced by the timing of order placement. The following rules will apply to all BLINCYTO® orders purchased via this method:

- DHL order cut-off for next business day delivery is 12 pm. Any orders received after 12 pm will be delivered on the following business day.
- Cold chain products are not dispatched on Fridays or the day before a public holiday.

It is also very important that the correct delivery details are set up with this dedicated account. During order placement, please ensure these details are accurately documented in the profile for your account. The following information may assist in the ordering process:

- Product description at DHL: BLINCYTO® 38.5mcg per vial, pack of 1
- List price: AUD $2904.77 ex GST per pack (vial)
- If you do not have an account number, please contact Amgen Medical Information: 1800 803 638

AMGEN®

BLINCYTO® (blinatumomab) infusion

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

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

Refer to full Product Information before prescribing – available from Amgen Australia Pty Ltd, Ph: 1800 803 638. www.amgen.com.au/Blincyto.PI

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 Precautions and Dosage and Administration*).

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/m^2 (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. 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

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