BLINCYTO® (blinatumomab)

Important Risk Minimisation Information for Patients and Caregivers

This educational brochure contains important information about BLINCYTO

This educational material is essential to ensure the safe and effective use of the medicine and appropriate management of the important selected adverse reactions. Please read it carefully before taking the medicine.

Please ensure you read the Consumer Medicine Information leaflet for further information on your treatment

If you have any questions about BLINCYTO, please speak to your doctor or nurse.

This information is not intended to replace discussions with your doctor or other health care professionals who are treating your acute lymphoblastic leukaemia. Read the BLINCYTO Consumer Medicine Information provided to you by your health care professional (HCP) before you start treatment. BLINCYTO Consumer Medicine Information is available at www.amgen.com.au/Blincyto.CMI

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

Important things to know about BLINCYTO

Infusion pump and its accessories	• You will receive BLINCYTO solution through an infusion that delivers the medicine directly through a tube inserted into a vein.
	• You will have the pump connected to you 24 hours a day for 28 days.
	• Make sure the tubing stays connected to the pump at all times.
	• **Do not let the tubing become tangled or twisted at any time.**
	• **Do not lie on the tubing.**
	• **Do not change the pump settings on purpose**:
	  ○ If the pump alarm goes off at any time, get help from your doctor or nurse immediately.
	  ○ If the pump stops working unexpectedly or if the infusion bag empties too quickly, get help from your doctor or nurse immediately.
	• **Do not pull the tubing or unplug the pump at any time.**
	• **If you notice blood in the tubing, get help from your doctor or nurse immediately.**
	• Keep the pump, the tubing, and the covering at the site where it is inserted into your vein dry at all times.
	• If you have any concerns regarding how your pump is working, please contact your doctor or nurse.

Nervous system problems	• BLINCYTO may make you feel dizzy, confused, or cause shaky hands, fits or trouble with walking, speaking or writing. • Call your doctor or nurse immediately if you experience these or any other unusual symptoms. For more information, see the Consumer Medicine Information. • **Do not drive your car, use heavy machinery or engage in hazardous activities while receiving this medicine**
Cytokine Release Syndrome	• When receiving BLINCYTO treatment, you might experience an event called cytokine release syndrome that can be caused by the destruction of cancer cells. • You may experience the following symptoms: fever, tiredness or weakness, low blood pressure, nausea, vomiting, skin rash, swelling or chills, shortness of breath, headache and dizziness. If any of the symptoms become severe or you experience any other unusual symptoms, please contact your doctor immediately

Patient Card

Please show this card to all emergency and healthcare providers

Information about BLINCYTO® (blinatumomab)

My name is _____

I am being treated with BLINCYTO, a treatment for acute lymphoblastic leukaemia, which can lower my immune system.

I started treatment on _____

Before providing any treatment, please call my prescribing doctor at the number below. If any medical evaluations are undertaken, please provide copies of all medical records, including any treatments and/or test results, to the doctor(s) named below.

	Name	Hospital	City	Phone Number
Haematologist Oncologist				
Haematology Nurse				

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

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

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/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.

BLINCYTO® (blinatumomab)

Level 7, 123 Epping Road, North Ryde NSW 2113.
Tel: 61 2 9870 1333, www.amgen.com.au
AU-12529. AMG3580. Prepared Februay 2020.

AMGEN®