▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

AUSTRALIAN PRODUCT INFORMATION

EPKINLY® (EPCORITAMAB) SOLUTION FOR INJECTION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS) can occur in patients receiving EPKINLY. Neurological toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), and serious and life-threatening reactions can occur in patients receiving EPKINLY.

Manage per section 4.2 Dose and method of administration, Dosage modifications and management of adverse reactions, in consultation with the patient's physician.

1. NAME OF THE MEDICINE

Epcoritamab

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

EPKINLY 4 mg/0.8 mL concentrate solution for injection: Each 0.8 mL single-dose vial contains 4 mg of epcoritamab.

EPKINLY 48 mg/0.8 mL solution for injection: Each 0.8 mL single-dose vial contains 48 mg of epcoritamab.

Epcoritamab is a humanised bispecific antibody that specifically binds to CD3+ T cells and CD20+ B cells. Epcoritamab is manufactured from two biological intermediates, which are produced in Chinese hamster ovary (CHO) cells using recombinant DNA technology.

Excipient with known effect

Each vial of EPKINLY contains 21.84 mg of sorbitol.

For the full list of excipients, see **Section 6.1 List of excipients**.

3. PHARMACEUTICAL FORM

EPKINLY is a sterile, preservative free, clear to slightly opalescent, colourless to slightly yellow solution, practically free of visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

EPKINLY is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. EPKINLY is not indicated for the treatment of patients with primary central nervous system lymphoma.

This medicine has **provisional approval** in Australia for the treatment of adult patients with relapsed or refractory DLBCL after two or more lines of systemic therapy. The decision to approve this indication has been made on the basis of overall response and duration of response from an uncontrolled, open label phase I/II study. Continued approval of this indication depends on verification and description of benefit in confirmatory trials.

4.2 Dose and method of administration

Recommended dosage

EPKINLY is for subcutaneous (SC) injection only. EPKINLY should be administered by an appropriately qualified healthcare professional. Administer EPKINLY according to the following schedule in 28-day cycles (see Table 1). The EPKINLY dosing schedule includes an initial priming dose of 0.16 mg on Cycle 1 Day 1, an intermediate dose of 0.8 mg on Cycle 1 Day 8, and a full dose of 48 mg administered from Cycle 1 Day 15 and onwards, according to Table 1.

Table 1: Dosing schedule

Dosing schedule	Cycle of treatment	Days	Epcoritamab dose (mg)[a]
Weekly	Cycle 1	1	0.16 mg (Priming dose)
		8	0.8 mg (Intermediate dose)
		15	48 mg (First full dose)
		22	48 mg
Weekly	Cycles 2 - 3	1, 8, 15, 22	48 mg
Every two weeks	Cycles 4 - 9	1, 15	48 mg
Every four weeks	Cycles 10 +	1	48 mg
[a]0.16 mg is a priming dose, 0.8 mg is an intermediate dose and 48 mg is a full dose.			

Administer EPKINLY until disease progression or unacceptable toxicity.

Pre-medications and prophylaxis

EPKINLY should be administered to adequately hydrated patients. Details on recommended pre-medication for cytokine release syndrome (CRS) is shown in Table 2.

Table 2: EPKINLY pre-medications

Cycle	Patient requiring pre-medication	Pre-medication	Administration
Cycle 1	All patients	Prednisolone (100 mg oral) or Dexamethasone (16 mg oral or 15 mg IV) or equivalent	• 30-120 minutes prior to each weekly administration of EPKINLY, and • for three consecutive days following each weekly administration of EPKINLY in Cycle 1
		• Diphenhydramine (50 mg oral) or equivalent • Paracetamol (1,000 mg oral)	• 30-120 minutes prior to the administration of EPKINLY
Cycle 2 and beyond	Patients who experienced Grade 2 or 3[a] CRS with previous dose	Prednisolone (100 mg oral) or Dexamethasone (16 mg oral or 15 mg IV) or equivalent	• 30-120 minutes prior to next administration of EPKINLY after a grade 2 or 3[a] CRS event, and • for three consecutive days following the next administration of EPKINLY until EPKINLY is given without subsequent CRS of Grade 2 or higher

[a] Patients should be permanently discontinued from EPKINLY after a Grade 4 CRS event.

Prophylaxis against *Pneumocystis jirovecii* pneumonia (PCP) and herpes virus infections is strongly recommended especially during concurrent use of steroids.

Monitor patients for potential CRS and immune effector cell-associated neurotoxicity syndrome (ICANS) following EPKINLY administrations during Cycle 1 and in subsequent cycles as needed at the physician's discretion. Following administration of the first full dose, patients should remain within close proximity to a healthcare facility that can assess and manage potential CRS and/or ICANS for at least 24 hours. Counsel patients on the signs and symptoms associated with CRS and ICANS and on seeking immediate medical attention should signs or symptoms occur at any time (see **Section 4.4 Special warnings and precautions for use; Cytokine release syndrome** and **Immune effector cell-associated neurotoxicity syndrome**).

Missed or delayed dose

A re-priming Cycle (identical to Cycle 1 with standard CRS prophylaxis) is required:

- If there are more than 8 days between the priming dose (0.16 mg) and intermediate dose (0.8 mg), or
- If there are more than 14 days between the intermediate dose (0.8 mg) and first full dose (48 mg), or
- If there are more than 6 weeks between full doses (48 mg).

After the re-priming cycle, the patient should resume treatment with Day 1 of the next planned treatment cycle (subsequent to the cycle during which the dose was delayed).

Dosage modifications and management of adverse reactions

Cytokine Release Syndrome (CRS)

Patients treated with EPKINLY may develop CRS. Evaluate for and treat other causes of fever, hypoxia, and hypotension. If CRS is suspected, manage according to the recommendations in Table 3. Patients who experience CRS should be monitored more frequently during next scheduled EPKINLY administrations.

Table 3: CRS grading and management guidance

Grade[a]	Recommended therapy	EPKINLY dose modification
Grade 1 • Fever (temperature ≥ 38°C) without hypotension or hypoxia	Provide supportive care such as antipyretics and intravenous hydration. **Anti-cytokine therapy:** Consider anti-cytokine therapy in certain cases, e.g., advanced age, high tumour burden, circulating tumour cells, fever refractory to antipyretics. Tocilizumab 8 mg/kg IV over 1 hour (not to exceed 800 mg per dose). Repeat tocilizumab after at least 8 hours as needed. Maximum of 2 doses in a 24-hour period. In case of concurrent ICANS choose alternative to tocilizumab (e.g., siltuximab, anakinra). See **Table 4.** **Corticosteroids** In case of concurrent ICANS, initiation of corticosteroids is highly recommended. Consider dexamethasone 10-20 mg per day (or equivalent).	Hold EPKINLY until resolution of CRS event.
Grade 2[b] • Fever (temperature ≥ 38°C) **AND** • Hypotension not requiring vasopressors **AND/OR** • Hypoxia requiring low-flow (≤6 L/minute) nasal cannula or blow-by	Provide supportive care such as antipyretics and intravenous hydration. **Anti-cytokine therapy:** Tocilizumab 8 mg/kg IV over 1 hour (not to exceed 800 mg per dose). Repeat tocilizumab after at least 8 hours as needed. Maximum of 2 doses in a 24-hour period. If CRS is refractory to initial anti-cytokine therapy, initiate/increase dose of corticosteroid therapy and consider alternative anti-cytokine therapy. In case of concurrent ICANS choose alternative to tocilizumab (e.g., siltuximab, anakinra). See **Table 4.** **Corticosteroids:** In case of concurrent ICANS, initiation of corticosteroids is highly recommended. Consider dexamethasone 10-20 mg per day (or equivalent).	Hold EPKINLY until resolution of CRS event.

Grade[a]	Recommended therapy	EPKINLY dose modification
Grade 3[b] • Fever (temperature ≥ 38°C) **AND** • Hypotension requiring 1 vasopressor with or without vasopressin **AND/OR** • Hypoxia requiring high-flow (>6 L/minute) nasal cannula, facemask, non-rebreather mask, or venturi mask	Provide supportive care such as antipyretics and intravenous hydration. **Anti-cytokine therapy** Tocilizumab 8 mg/kg IV over 1 hour (not to exceed 800 mg per dose). Repeat tocilizumab after at least 8 hours as needed. Maximum of 2 doses in a 24-hour period. If CRS is refractory to initial anti-cytokine therapy, initiate/increase dose of corticosteroid therapy and consider alternative anti-cytokine therapy. In case of concurrent ICANS choose alternative to tocilizumab (e.g., siltuximab, anakinra). See **Table 4.** **Corticosteroids:** Dexamethasone (e.g., 10-20 mg IV every 6 hours). If no response, initiate methylprednisolone 1000 mg/day.	Hold EPKINLY until resolution of CRS event.
Grade 4 • Fever (temperature ≥ 38°C) **AND** • Hypotension requiring ≥ 2 vasopressors (excluding vasopressin) **AND/OR** • Hypoxia requiring positive pressure ventilation (e.g. CPAP, BiPAP, intubation and mechanical ventilation)	Provide supportive care such as antipyretics and intravenous hydration. **Anti-cytokine therapy** Tocilizumab 8 mg/kg IV over 1 hour (not to exceed 800 mg per dose). Repeat tocilizumab after at least 8 hours as needed. Maximum of 2 doses in a 24-hour period. If CRS is refractory to initial anti-cytokine therapy, initiate/increase dose of corticosteroid therapy and consider alternative anti-cytokine therapy. In case of concurrent ICANS choose alternative to tocilizumab (e.g., siltuximab, anakinra). See **Table 4.** **Corticosteroids** Dexamethasone (e.g., 10-20 mg IV every 6 hours). If no response, initiate methylprednisolone 1000 mg/day.	Permanently discontinue EPKINLY.

[a] CRS graded according to ASTCT consensus criteria (Lee et al., 2019)
[b] If Grade 2 or 3 CRS occurs with the second full dose or beyond, administer CRS prophylaxis with each subsequent dose until EPKINLY dose is given without subsequent CRS (of any grade).

Immune effector cell-associated neurotoxicity syndrome (ICANS)

Monitor patients for signs and symptoms of ICANS. Rule out other causes of neurologic symptoms. If ICANS is suspected, manage according to the recommendations in Table 4.

Table 4: ICANS grading and management guidance

Grade[a]	Recommended therapy	EPKINLY dose modification
Grade 1 ICE score[c] 7-9[b] or, depressed level of consciousness[b]: awakens spontaneously	Dexamethasone, 10 mg IV every 12 hours. Consider non-sedating anti-seizure medication (e.g., levetiracetam) until resolution of ICANS. <u>Anti-cytokine therapy</u> *No concurrent CRS*: Anti-cytokine therapy not recommended. *Concurrent CRS*: Anti-cytokine therapy recommended. Choose alternative to tocilizumab (e.g., siltuximab, anakinra) if possible. • Consider anakinra as a daily dose of 100 mg SC or 200 mg SC (100 mg every 12 hours) depending on the severity of neurotoxicity and other concurrent toxicities. Anakinra should be given until resolution of neurotoxicity and other concurrent toxicities which could benefit from anakinra treatment. • Consider siltuximab, 11 mg/kg IV over 1 hour, one time only.	Hold EPKINLY until resolution of event.
Grade 2 ICE score[c] 3-6 or, depressed level of consciousness[b]: awakens to voice	Dexamethasone at 10-20 mg IV every 12 hours. Consider non-sedating anti-seizure medication (e.g., levetiracetam) until resolution of ICANS. <u>Anti-cytokine therapy:</u> *No concurrent CRS:* Anti-cytokine therapy not recommended. *Concurrent CRS:* Anti-cytokine therapy recommended. Choose alternative to tocilizumab (e.g., siltuximab, anakinra) if possible. • Consider anakinra as a daily dose of 100 mg SC or 200 mg SC (100 mg every 12 hours) depending on the severity of neurotoxicity and other concurrent toxicities. Anakinra should be given until resolution of neurotoxicity and other concurrent toxicities which could benefit from anakinra treatment. • Consider siltuximab, 11 mg/kg IV over 1 hour, one time only.	Hold EPKINLY until resolution of event.

Grade[a]	Recommended therapy	EPKINLY dose modification
Grade 3 ICE score[c] 0-2 or, depressed level of consciousness[b]: awakens only to tactile stimulus, or seizures[b], either: • any clinical seizure, focal or generalised that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local oedema[b] on neuroimaging[c]	Dexamethasone 10-20 mg IV every 6 hours. If no response, initiate methylprednisolone 1000 mg/day. Consider non-sedating anti-seizure medication (e.g., levetiracetam) until resolution of ICANS. <u>Anti-cytokine Therapy</u> *No concurrent CRS:* Anti-cytokine therapy not recommended. *Concurrent CRS:* Anti-cytokine therapy recommended. Choose alternative to tocilizumab (e.g., siltuximab, anakinra) if possible. • Consider anakinra as a daily dose of 100 mg SC or 200 mg SC (100 mg every 12 hours) depending on the severity of neurotoxicity and other concurrent toxicities. Anakinra should be given until resolution of neurotoxicity and other concurrent toxicities which could benefit from anakinra treatment. • Consider siltuximab, 11 mg/kg IV over 1 hour, one time only.	**First episode:** Delay EPKINLY until full resolution of event. **Second episode:** permanently discontinue EPKINLY.
Grade 4 ICE score[b,c] 0 or, depressed level of consciousness[b] either: • patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • stupor or coma, or seizures[b], either: • life-threatening prolonged seizure (> 5 minutes), or • repetitive clinical or electrical seizures without return to baseline in between, or motor findings[b]: • deep focal motor weakness such as hemiparesis or paraparesis, or • raised intracranial pressure / cerebral oedema[b], with signs/symptoms such as: o diffuse cerebral oedema on neuroimaging, or o decerebrate or decorticate posturing, or o cranial nerve VI palsy, or o papilloedema, or o Cushing's triad	Dexamethasone 10-20 mg IV every 6 hours. If no response, initiate methylprednisolone 1000 mg/day. Consider non-sedating anti-seizure medication (e.g., levetiracetam) until resolution of ICANS. <u>Anti-cytokine therapy</u>: *No concurrent CRS:* Anti-cytokine therapy not recommended. *Concurrent CRS:* Anti-cytokine therapy recommended. Choose alternative to tocilizumab (e.g., siltuximab, anakinra) if possible. • Consider anakinra as a daily dose of 100 mg SC or 200 mg SC (100 mg every 12 hours) depending on the severity of neurotoxicity and other concurrent toxicities. Anakinra should be given until resolution of neurotoxicity and other concurrent toxicities which could benefit from anakinra treatment. • Consider siltuximab, 11 mg/kg IV over 1 hour, one time only.	Permanently discontinue EPKINLY.

Grade[a]	**Recommended therapy**	**EPKINLY dose modification**

[a] ICANS graded according to ASTCT ICANS Consensus Grading (Lee et al., 2019)
[b] ICANS grade is determined by the most severe event (ICE score, level of consciousness, seizures, motor findings, raised ICP/cerebral oedema) not attributable to any other cause
[c] If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: Orientation (oriented to year, month, city, hospital = 4 points); Naming (name 3 objects, e.g., point to clock, pen, button = 3 points); Following Commands (e.g., "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); Writing (ability to write a standard sentence = 1 point); and Attention (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points

Other adverse reactions

See Table 5 for recommended dosage modifications for other adverse reactions.

Table 5: Recommended dosage modifications for other adverse reactions

Adverse Reaction[a]	**Severity**[a]	**Action**
Infections	Grades 1-4	• Withhold EPKINLY in patients with active infection, until the infection resolves • For Grade 4, consider permanent discontinuation of EPKINLY
Neutropenia or febrile neutropenia	Absolute neutrophil count less than 0.5 x 10^9/L	• Withhold EPKINLY until absolute neutrophil count is 0.5 x 10^9/L or higher
Thrombocytopenia	Platelet count less than 50 x 10^9/L	• Withhold EPKINLY until platelet count is 50 x 10^9/L or higher
Other adverse reactions	Grade 3 or higher	• Withhold EPKINLY until the toxicity resolves to Grade 1 or baseline

[a] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), Version 5.0.

Preparation and administration

EPKINLY should be prepared and administered by a healthcare provider as subcutaneous injection (SC). Each vial of EPKINLY is for single use in one patient only.

The administration of EPKINLY takes place over the course of 28-day cycles, following the dosing scheduled in **Section 4.2 Dose and method of administration; Recommended dosage**. Inspect visually for particulate matter and discolouration prior to administration. EPKINLY injection is a colourless to slightly yellow solution. Do not use if the solution is discoloured, or cloudy, or if foreign particles are present.

Dose preparation

Use aseptic technique to prepare EPKINLY. Filtration of the diluted solution is not required.

Preparation instructions for 0.16 mg and 0.8 mg doses of EPKINLY

0.16 mg priming dose preparation instructions - *(2 dilutions required)*

Use an appropriately sized syringe, vial and needle for each transfer step.

1) Prepare EPKINLY vial a) Retrieve one 4 mg/0.8 mL EPKINLY vial from the refrigerator. b) Allow the vial to come to room temperature for no more than 1 hour. c) Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial.
2) Perform first dilution a) Label an appropriately sized empty vial as **"Dilution A"**. b) Transfer **0.8 mL of EPKINLY** into the **Dilution A** vial. c) Transfer **4.2 mL of 0.9% Sodium Chloride Injection, sterile solution,** into the **Dilution A** vial. d) Gently swirl the **Dilution A** vial for 30 – 45 seconds.
3) Perform second dilution a) Label an appropriately sized empty vial as **"Dilution B"**. b) Transfer **2 mL of solution** from the **Dilution A** vial into the **Dilution B** vial. The **Dilution A** vial is no longer needed. c) Transfer **8 mL of 0.9% Sodium Chloride Injection, sterile solution** into the **Dilution B** vial to make a final concentration of 0.16 mg/mL. d) Gently swirl the **Dilution B** vial for 30 – 45 seconds.
4) Withdraw dose a) Withdraw **1 mL of the diluted EPKINLY** from the **Dilution B** vial into a syringe.
5) Label syringe Label the syringe with the drug name, dose strength (0.16 mg) and the time of day.

Discard the vial and any unused portion of EPKINLY in accordance with local requirements.

0.8 mg intermediate dose preparation instructions - *(1 dilution required)*

Use an appropriately sized syringe, vial and needle for each transfer step.

1) Prepare EPKINLY vial a) Retrieve one 4 mg/0.8 mL EPKINLY vial from the refrigerator. b) Allow the vial to come to room temperature for no more than 1 hour. c) Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial.
2) Perform dilution a) Label an appropriately sized empty vial as **"Dilution A"**. b) Transfer **0.8 mL of EPKINLY** into the **Dilution A** vial. c) Transfer **4.2 mL of 0.9% Sodium Chloride Injection, sterile solution** into the **Dilution A** vial to make a final concentration of 0.8 mg/mL. d) Gently swirl the **Dilution A** vial for 30 – 45 seconds.
3) Withdraw dose a) Withdraw **1 mL of the diluted EPKINLY** from the **Dilution A** vial into a syringe.
4) Label syringe Label the syringe with the drug name, dose strength (0.8 mg) and the time of day.

Discard the vial and any unused portion of EPKINLY in accordance with local requirements.

48 mg full dose preparation instructions *(No dilution required)*

EPKINLY 48mg/0.8mL vial is supplied as ready-to-use solution that does not need dilution prior to administration.

1) Prepare EPKINLY vial a) Retrieve one 48 mg/0.8 mL EPKINLY vial from the refrigerator. b) Allow the vial to come to room temperature for no more than 1 hour. c) Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial.
2) Withdraw dose Withdraw **0.8 mL of the EPKINLY** into a syringe.
3) Label syringe Label the syringe with the drug name, dose strength (48 mg) and the time of day.

Discard the vial and any unused portion of EPKINLY in accordance with local requirements.

Storage for diluted and prepared EPKINLY

To reduce microbiological hazard, use as soon as practical after dilution. If storage is necessary, hold at 2-8˚C for not more than 24 hours. Within these 24 hours, the EPKINLY solution can be stored for up to 12 hours at room temperature from the start of dose preparation to administration. Minimise exposure to daylight. Allow EPKINLY solution to equilibrate to room temperature before administration. Discard unused EPKINLY solution beyond the allowable storage time.

Site Administration

The injection site should be preferably in the lower part of abdomen or the thigh. Change of injection site from left or right side or vice versa is recommended especially during the weekly administration (Cycles 1-3).

4.3 Contraindications

Hypersensitivity to epcoritamab, or to any of the excipients listed in Section 6.1.

4.4 Special warnings and precautions for use

Cytokine release syndrome

Cytokine release syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving epcoritamab. The most common signs and symptoms of CRS include pyrexia, hypotension and hypoxia. Other signs and symptoms of CRS in greater than two patients includes chills, tachycardia, headache and dyspnoea.

The median time to onset of CRS from the most recent administered epcoritamab dose was 2 days (range: 1 to 11 days). The median time to onset after the first full dose was 20.6 hours (range: 0.2 days to 7 days). Most CRS events occurred in Cycle 1 and were associated with the first full dose of EPKINLY. The median duration of CRS was 2 days (range: 1 to 27 days). Administer prophylactic corticosteroids to mitigate the risk of CRS (see **Section 4.2 Dose and**

method of administration; Pre-medications and prophylaxis).

Monitor patients for potential CRS following epcoritamab administrations during Cycle 1 and in subsequent cycles as needed at the physician's discretion. For at least 24 hours following administration of the first full dose, patients should remain within close proximity to a healthcare facility that can assess and manage potential CRS. At the first signs or symptoms of CRS, institute treatment of supportive care with tocilizumab and/or corticosteroids as appropriate. Counsel patients on the signs and symptoms associated with CRS and instruct patients to contact their healthcare professional and seek immediate medical attention should signs or symptoms occur at any time. Management of CRS may require either temporary delay or discontinuation of epcoritamab based on the severity of CRS (see **Section 4.2 Dose and method of administration; Dosage modifications and management of adverse reactions)**.

Immune effector cell-associated neurotoxicity syndrome

Immune effector cell-associated neurotoxicity syndrome (ICANS), including a fatal event, have occurred in patients receiving epcoritamab. ICANS may manifest as aphasia, altered level of consciousness, impairment of cognitive skills, motor weakness, seizures, and cerebral oedema.

The median time to onset of ICANS from the start of epcoritamab treatment (Cycle 1 Day 1) was 16.5 days (range: 8 to 141 days). The majority of cases of ICANS occurred within the Cycle 1 of epcoritamab treatment, however some occurred with delayed onset. The median duration of ICANS was 5 days (range: 1, 9 days). The onset of ICANS can be concurrent with CRS, following resolution of CRS or in the absence of CRS.

Monitor patients for signs and symptoms of ICANS following epcoritamab administrations during Cycle 1 and in subsequent cycles as needed at the physician's discretion. Following administration of the first full dose, patients should remain within close proximity to a healthcare facility that can assess and manage potential ICANS for at least 24 hours. At the first signs or symptoms of ICANS institute treatment with corticosteroids and non-sedating-anti-seizure medications as appropriate (see **Section 4.2 Dose and method of administration**; **Dosage modifications and management of adverse reactions**). Counsel patients on the signs and symptoms of ICANS and that the onset of events may be delayed. Instruct patients to contact their healthcare professional and seek immediate medical attention should signs or symptoms occur at any time. Delay or discontinue EPKINLY as recommended (see Section 4.2 Dose and method of administration; Dosage modifications and management of adverse reactions).

Serious infections

Treatment with EPKINLY may lead to an increased risk of infections. Serious infections, including fatal infections were observed in patients treated with epcoritamab in clinical trials (see **Section 4.8 Adverse effects (undesirable effects)**).

Avoid administration of EPKINLY in patients with clinically significant active systemic infections. As appropriate, administer prophylactic antimicrobials (see **Section 4.2 Dose and method of administration; Pre-medications and prophylaxis**). Monitor patients for signs and symptoms of infections prior to and during treatment and treat according to standard/local guidelines and practice. In the event of febrile neutropenia, patients should be evaluated for infection and managed according to local guidelines.

Immunisation

Live and/or live-attenuated vaccines should not be given concurrently with EPKINLY. Studies have not been conducted in patients who received live vaccines.

Patient card

The doctor must inform the patient of the risk of CRS and ICANS and any signs and symptoms of CRS and ICANS. Patients must be instructed to seek immediate medical attention if they experience signs and symptoms of CRS and/or ICANS. Patients should be provided with a patient card and instructed to carry the card at all times. This card describes symptoms of CRS and ICANS which, if experienced, should prompt the patient to seek immediate medical attention.

Use in hepatic impairment

Dose adjustments are not considered necessary in patients with mild hepatic impairment. No dose recommendations can be made for patients with moderate to severe hepatic impairment.

Use in renal impairment

Dose adjustments are not considered necessary in patients with mild to moderate renal impairment. No dose recommendations can be made for patients with severe renal impairment to end-stage renal disease.

Use in the elderly

In patients with DLBCL in EPCORE NHL-1, 44 (32%) were ≥65 to <75 years of age and 29 (21%) were ≥75 years of age. No clinically meaningful differences in safety or efficacy were observed between patients ≥65 years of age compared with younger adult patients.

Paediatric use

The safety and efficacy of EPKINLY in children aged less than 18 years of age have not yet been established.

Effects on laboratory tests

Grade 3 or 4 laboratory abnormalities worsening from baseline reported in at least 10% of patients with LBCL within the EPCORE NHL-1 study were lymphocyte count decreased (78%), neutrophil count decreased (31%), haemoglobin decreased (13%), and platelets decreased (13%).

4.5 Interactions with other medicines and other forms of interactions

No formal drug interaction studies have been conducted with EPKINLY.

Elevation of certain proinflammatory cytokines by EPKINLY may suppress CYP450 enzyme activities. On initiation of EPKINLY therapy in patients being treated with CYP450 substrates with a narrow therapeutic index, therapeutic monitoring should be considered.

4.6 Fertility, pregnancy and lactation

Females of reproductive potential

Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY treatment. Females of reproductive potential should use effective contraception during treatment with EPKINLY and for at least 4 months after the last dose.

Effects on fertility

No animal fertility studies have been conducted with epcoritamab. The effect of EPKINLY on male and female fertility is unknown.

Use in pregnancy

Pregnancy Category C

Female patients of reproductive potential must be advised to avoid pregnancy while receiving EPKINLY and apprised of the potential risk to the fetus.

There are no data on the use of EPKINLY in pregnant women. Embryofetal development studies have not been conducted with epcoritamab in animals.

Based on its mechanism of action, EPKINLY may cause fetal harm, including B-cell lymphocytopenia and alterations in normal immune responses, when administered to pregnant women. IgG1 antibodies, such as epcoritamab, can cross the placenta resulting in

fetal exposure. Fetal B-cell depletion poses a risk of opportunistic infections in the neonate. Epcoritamab-induced cytokine release may also pose a risk for embryofetal loss. The risk of malformations is considered to be low.

Postponing vaccination with live or live attenuated vaccines is recommended for neonates and infants who have been exposed to epcoritamab *in utero* until B-cell levels have recovered.

Use in lactation

It is not known whether epcoritamab is excreted in human milk or its effect on milk production. Since IgGs are known to be present in milk, neonatal exposure to epcoritamab may occur via lactational transfer. Breast feeding should be discontinued during treatment with EPKINLY and for at least 4 months after the last dose.

4.7 Effects on ability to drive and use machines

No formal studies on the effect of EPKINLY on the ability to drive and operate machines have been performed. Due to the potential for ICANS, patients should be advised to exercise caution while (or avoid if symptomatic) driving or using heavy or potentially dangerous machines.

4.8 Adverse effects (undesirable effects)

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at https://www.tga.gov.au/reporting-problems.

Clinical trial experience

EPCORE NHL-1

The safety of EPKINLY was evaluated in a non-randomised, single-arm study in 167 patients with relapsed or refractory LBCL, including 148 patients with DLBCL, after two or more lines of systemic therapy and included all patients who enrolled to the 48 mg dose and received at least one dose of EPKINLY.

The median duration of exposure to EPKINLY was 3.7 months (range: 0 to 20 months).

Serious adverse reactions occurred in 40% of patients; the most frequent serious adverse reaction (≥ 10%) was CRS (31%). Two patients (1.2%) experienced a fatal adverse reaction; one each for ICANS and pneumonia.

Discontinuation due to adverse reactions occurred in 2.4% of patients. Discontinuation of epcoritamab due to pneumonia occurred in 2 patients and discontinuation due to CRS or ICANS occurred in 1 patient (each).

Dose delays due to adverse reactions occurred in 20% of patients. Adverse reactions leading to dose delays (≥ 3%) were CRS (7.2%), neutropenia (4.2%), pyrexia (3.0%), and thrombocytopenia (3.0%).

Table 6 provides adverse reactions reported in patients with relapsed or refractory LBCL. Adverse reactions are listed by MedDRA body system organ class, rate, and frequency.

Frequencies are defined as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Table 6: Adverse reactions reported in patients with relapsed or refractory LBCL treated with EPKINLY in EPCORE NHL-1 study

Adverse Reaction by Body System	EPKINLY (N=167)		
	All grades frequency	All grades (%)	Grade ≥3 (%)
Blood and lymphatic system disorders			
Neutropenia[a]	Very common	28	22
Anaemia[b]	Very common	19	10
Thrombocytopenia[c]	Very common	15	7.2
Febrile neutropenia	Common	2.4	2.4
Gastrointestinal disorders			
Nausea	Very common	20	1.2
Diarrhoea	Very common	20	
Vomiting	Very common	12	0.6
General disorders and administration site conditions			
Injection site reactions[d]	Very common	30	
Pyrexia[e]	Very common	23	
Immune system disorders			
Cytokine release syndrome[f]	Very common	50	2.4
Infections and infestations			
Pneumonia[g]	Common	7.2	3.6
Upper respiratory tract infection[h]	Common	6.0	1.2
Metabolism and nutrition disorders			
Tumour lysis syndrome[i]	Common	1.8	1.8
Neoplasm benign, malignant and unspecified (including cysts and polyps)			
Tumour flare	Common	3.0	
Nervous system disorders			
Headache	Very common	13	0.6
Immune effector cell-associated neurotoxicity syndrome (ICANS)[f]	Common	6.0	0.6
Skin and subcutaneous tissue disorders			
Rash[j]	Common	7.8	
Pruritus	Common	6.6	

Events were graded using NCI CTCAE version 5.0.
CRS events were graded using ASTCT consensus criteria (Lee et. al., 2019).
[a] Neutropenia includes neutropenia and neutrophil count decreased.
[b] Anaemia includes anaemia and serum ferritin decreased.
[c] Thrombocytopenia includes platelet count decreased and thrombocytopenia.
[d] Injection site reactions include injection site bruising, injection site erythema, injection site hypertrophy, injection site inflammation, injection site mass, injection site pain, injection site pruritis, injection site rash, injection site reaction, injection site swelling and injection site urticaria.
[e] Pyrexia includes pyrexia and body temperature increased.
[f] Events graded using American Society for Transplant and Cellular Therapy consensus criteria.
[g] Pneumonia includes COVID-19 pneumonia and pneumonia.
[h] Upper respiratory tract infection includes laryngitis, pharyngitis, respiratory syncytial virus infection, rhinitis, rhinovirus infection, and upper respiratory tract infection.
[i] Clinical Tumour Lysis Syndrome was graded based on Cairo-Bishop.
[j] Rash includes rash, rash erythematous, rash maculo-papular and rash pustular.

Table 7 summarises laboratory abnormalities in EPCORE NHL-1.

Table 7: Laboratory abnormalities worsening from baseline, with Grade 3 to 4 occurring in ≥ 10% of patients with relapsed or refractory LBCL who received EPKINLY in EPCORE NHL-1 study

Laboratory Abnormality*	EPKINLY[1] (N=167)	
	All Grades (%)	Grade 3 or 4 (%)
Haematology		
Lymphocyte count decreased	87	78
Haemoglobin decreased	62	13
Neutrophils decreased	49	31
Platelets decreased	49	13

* Laboratory abnormalities were graded based on CTCAE Version 5.0
[1] The denominator used to calculate the rate varied from 156 to 163 based on the number of patients with a baseline value and at least one post-treatment value.

Important adverse reactions

Cytokine release syndrome (CRS)

CRS of any grade occurred in 50% (84/167) of patients treated with EPKINLY. The incidence of Grade 1 was 31% (52/167), Grade 2 was 17% (28/167), and Grade 3 was 2.4% (4/167). The median time to onset of CRS from the most recent administered EPKINLY dose was 2 days (range: 1 to 11 days). CRS resolved in 98.8% of patients, and the median duration of CRS events was 2 days (range 1 to 27 days).

The most common signs and symptoms of CRS included pyrexia 50% (83/167), hypotension 16% (26/167) and hypoxia 9.6% (16/167). Other signs and symptoms of CRS in greater than two patients included chills (4.8%), tachycardia (including sinus tachycardia [7.8%]), headache (13%) and dyspnoea (7.8%). In addition to corticosteroids use, tocilizumab was used to manage CRS event in 15% of patients.

Immune effector cell-associated neurotoxicity syndrome (ICANS)

ICANS occurred in 6% of patients treated with EPKINLY; 4.2% experienced Grade 1 and 1.2% experienced Grade 2. One patient (0.6%) experienced an ICANS event of Grade 5 (fatal). The

median time to first ICANS onset from the start of EPKINLY treatment was 16.5 days (range: 8 to 141 days). ICANS resolved in 90% (9/10) of patients with supportive care. The median time to resolution of ICANS was 5 days (range: 1 to 9 days).

Serious Infections

Serious infections occurred in 16% of patients treated with EPKINLY. The most frequent serious infections were pneumonia (2.4%), sepsis (2.4%), COVID-19 (1.8%), COVID-19 pneumonia (1.8%), bacteraemia (1.2%), septic shock (1.2%), and upper respiratory tract infection (1.2%). Fatal serious infections occurred in 4 (2.4%) patients.

Immunogenicity

Epcoritamab has the potential to induce anti-drug-antibodies (ADA). The incidence of antibodies to epcoritamab was low and all the patients who were positive had low titres (≥1 in 0.6% (1/158)). Due to the low number of patients with ADAs, a meaningful analysis of the impact of ADAs on safety is limited (see **Section 5.2 Pharmacokinetic properties; Special populations**).

4.9 Overdose

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia). In the event of overdose, monitor the patient for any signs or symptoms of adverse reactions and administer appropriate supportive treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other monoclonal antibodies and antibody-drug conjugates

ATC code: L01FX27

Epcoritamab induced depletion of circulating B cells (defined as CD19+ B-cell counts < 10 cell/µl in subjects who have detectable B cells at treatment initiation) after the first full dose (48 mg) which was sustained while patients remained on treatment. Subsequent treatment with epcoritamab induced expansion and activation of circulating T cells from baseline.

Following subcutaneous administration of epcoritamab, transient and modest elevations of circulating levels of selected cytokines (IFN-γ, TNFα, IL-6, IL-2, and IL-10) occurred, mostly after the first full dose (48 mg) with peak levels between 1 to 4 days. Levels returned to baseline prior to the subsequent full dose.

Mechanism of action

Epcoritamab is a humanised IgG1-bispecific antibody that binds to a specific extracellular epitope of CD20 on B cells and to CD3 on T cells. CD20 is expressed on most human B-cell lymphomas and leukaemias and on B cells in peripheral blood, but not haematopoietic stem cells or plasma cells. The activity of epcoritamab is dependent upon simultaneous engagement of CD20-expressing cancer cells and CD3-expressing endogenous T cells by epcoritamab that induces specific T-cell activation and T-cell-mediated killing of CD20-expressing cells, as epcoritamab does not have direct immune effector mechanisms.

The Fc region of epcoritamab is silenced for direct immune effector mechanisms, such as antibody-dependent cellular cytotoxicity (ADCC), complement-dependent cellular cytotoxicity (CDC), and antibody-dependent cellular phagocytosis (ADCP).

Clinical trials

EPCORE NHL-1

Study EPCORE NHL-1 was an open-label, multi-cohort, multicentre, single-arm trial that evaluated epcoritamab as monotherapy in patients with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL). The study includes a dose escalation part and an expansion part. The expansion part of the study included an aggressive non-Hodgkin lymphoma (aNHL) cohort, an indolent NHL (iNHL) cohort and a mantle-cell lymphoma (MCL) cohort. The pivotal cohort consisted of patients with DLBCL (N=139).

The study excluded patients with CNS involvement of lymphoma**,** allogeneic haematopoietic stem cell transplantation (HSCT) or solid organ transplant, ongoing active infectious diseases, any patients with known impaired T-cell immunity, a creatinine clearance of less than 45 mL/min, alanine aminotransferase >3 times the upper limit of normal and cardiac ejection fraction less than 45%. Efficacy was evaluated in 139 patients with DLBCL who had received the 48 mg full dose of EPKINLY subcutaneously (SC) in cycles of 4 weeks, i.e., 28 days. Epcoritamab was administered as a monotherapy as follows:

- Cycle 1: EPKINLY 0.16 mg on Day 1, 0.8 mg on Day 8, 48 mg on Day 15 and Day 22
- Cycles 2-3: EPKINLY 48 mg on Days 1, 8, 15, and 22
- Cycles 4-9: EPKINLY 48 mg on Days 1 and 15
- Cycles 10 and beyond: EPKINLY 48 mg on Day 1

Patients continued to receive EPKINLY until disease progression or unacceptable toxicity.

The demographics and baseline characteristics are shown in Table 8.

Table 8: Demographics and baseline characteristics of patients with DLBCL in EPCORE NHL-1 study

Characteristics	**(N=139)**
Age	
Median, years (min, max)	66 (22, 83)
Males, (%)	61
Race	
White; %	60
Black, or African American; %	0
Asian; %	19
Other; %	4
Not Reported; %	17
ECOG performance status; %	
0	48
1	48
2	3.6
Number of prior lines of anti-lymphoma therapy, %	
Median (min, max)	3 (2, 11)
2	30
3	34
≥4	37
Disease type at study entry; (%)	
DLBCL	100
DLBCL Disease history; %	
De Novo DLBCL	70
DLBCL transformed from indolent lymphoma	29
FISH Analysis Per Central lab, N=88	
Double-hit/Triple-hit lymphoma, (%)	14
Prior Therapy; (%)	
Prior CAR-T	38
Prior autologous HSCT	19
Primary refractory disease[a]	59
Refractory to ≥ 2 consecutive lines of prior anti-lymphoma therapy[b]	75
Refractory to the last line of systemic antineoplastic therapy[b]	82
Refractory to anti-CD20 therapy in last line	84
Refractory to CAR-T	28
Polatuzumab vedotin	9
Topoisomerase inhibitor	67

CAR-T = chimeric antigen receptor T-cell; DLBCL = diffuse large B-cell lymphoma; ECOG = Eastern Cooperative Oncology Group; FISH = fluorescence in situ hybridization; HSCT= haematopoietic stem cell transplantation.
[a] A patient is considered to be primary refractory if they are refractory to frontline anti-lymphoma therapy.
[b] A patient is considered to be refractory if they experience disease progression or stable disease as best response or disease progression within 6 months after therapy completion.

Efficacy was established based on overall response rate (ORR) determined by Lugano criteria (2014) as assessed by Independent Review Committee (IRC). The median follow-up time was 11 months (range: 0.3 to 17.9 months).

Table 9: Efficacy results in study EPCORE NHL-1 in patients with DLBCL

Endpoint [a] **IRC assessment**	**EPKINLY** **(N=139)**
ORR, n (%)	86 (62)
(95% CI)	(53.3, 70)
CR, n (%)	54 (39)
(95% CI)	(30.7, 47.5)
PR, n (%)	32 (23)
DOR	
Median (95% CI), months	12 (6.6, NR)
6-month estimate, % (95% CI)	63 (51.5, 73)
9-month estimate, % (95% CI)	62 (49.7, 71.5)
DOCR	
Median (95% CI), months	12 (9.7, NR)
6-month estimate, % (95% CI)	85 (70, 93.2)
9-month estimate, % (95% CI)	85 (70, 93.2)
DOR if Best Response is CR	
Median (95% CI), months	NR (12, NR)
6-month estimate, % (95% CI)	88 (74.6, 94.3)
9-month estimate, % (95% CI)	88 (74.6, 94.3)
TTR, median (range), months	1.4 (1, 8.4)

CI = confidence interval; CR = complete response; DOR = duration of response; DOCR = duration of complete response; IRC = independent review committee; NR = not reached; ORR = overall response rate; PR = partial response; TTR = time to response.
[a] Determined by Lugano criteria (2014) as assessed by independent review committee (IRC)

The median time to CR was 2.7 months (range: 1.2 to 11.1 months).

Response durations were longer in patients who achieved CR, as compared to patients with a best response of partial response (PR) (Table 9).

The overall response rates and complete response rates with EPKINLY were consistent across the following subgroups: age, number of or response to prior lines of therapy, and prior CAR-T experience.

In subgroup analysis of patients (n = 53) who received CAR-T, the ORR was 53% (95% CI: 39, 67), and the CR rate was 34% (95% CI: 22, 48). Median duration of response for these patients was 9.7 months (95% CI: 5.4, NR), and the median progression-free survival was 2.7 months (95% CI: 1.4, 11).

In subgroup analysis of patients (n = 86) with no prior CAR-T, the ORR was 67% (95% CI: 56, 77), and the CR rate was 42% (95% CI: 31, 53). Median duration of response for these patients was 12 months (95% CI: 5.6, NR); and the median progression-free survival was 5.4 months (95% CI: 3.7, NR).

In a pre-specified subgroup analysis of patients (n = 82) who were primary refractory to anti-lymphoma therapy, the ORR was 54% (95% CI: 42, 65), and the CR rate was 30% (95% CI: 21, 42).

Median overall survival (OS) for patients on EPKINLY was not reached.

5.2 Pharmacokinetic properties

The population pharmacokinetics (PK) following subcutaneous administration of epcoritamab was described by a two-compartment model with first order subcutaneous absorption and target-mediated drug elimination. The moderate to high pharmacokinetic variability for epcoritamab was observed and characterised by inter-individual variability (IIV) ranging from 25.7% to 137.5% coefficient of variation (CV) for epcoritamab PK parameters.

Following the recommended SC dose of epcoritamab 48 mg, the geometric mean (% CV) C_{max} of epcoritamab is 10.8 µg/mL (41.7%) and $AUC_{0\text{-}7d}$ is 68.9 day*µg/mL (45.1%) at the end of the weekly dosing schedule.

The geometric mean (% CV) C_{max} of epcoritamab is 7.52 µg/mL (41.1%) and $AUC_{0\text{-}14d}$ is 82.6 day*µg/mL (49.3%) at the end of every two weeks dosing schedule.

The geometric mean (% CV) C_{max} of epcoritamab is 4.76 µg/mL (51.6%) and $AUC_{0\text{-}28d}$ is 74.3 day*µg/mL (69.5%) at steady state during every 4-week dosing schedule.

Absorption

The peak concentrations occurred around 3-4 days (T_{max}) in patients receiving the 48 mg full dose.

Distribution

The geometric mean (% CV) central volume of distribution is 8.27 L (27.5%) based on population PK modelling.

Metabolism

The metabolic pathway of epcoritamab has not been directly studied. Like other protein therapeutics, epcoritamab is expected to be degraded into small peptides and amino acids via catabolic pathways.

Excretion

Epcoritamab is expected to undergo saturable target mediated clearance. The geometric mean (% CV) clearance (L/day) is 0.441 (27.8%). The half-life of epcoritamab is concentration dependent. The population PK model-derived geometric mean half-life of full dose epcoritamab (48 mg) ranged from 22 to 25 days based on frequency of dosing.

Special populations

No clinically important effects on the pharmacokinetics of epcoritamab were observed based on age (20 to 89 years), sex, or race/ethnicity (White, Asian, and Other), mild to moderate renal impairment (CrCl ≥30 mL/min to CrCl <90 mL/min), and mild hepatic impairment (total bilirubin ≤ ULN and AST > ULN, or total bilirubin 1 to 1.5 times ULN and any AST) after accounting for differences in bodyweight. No patients with severe to end-stage renal disease (CrCl <30mL/min) or severe hepatic impairment (total bilirubin > 3 times ULN and any AST) have been studied. There is very limited data in moderate hepatic impairment (total bilirubin >1.5 to 3 times ULN and any AST). Therefore, the pharmacokinetics of epcoritamab are unknown in these populations.

Like other therapeutic proteins, body weight (39 to 144 kg) has a statistically significant effect on the pharmacokinetics of epcoritamab, however this effect is not clinically relevant across body weight categories (< 65 kg, 65 - < 85 kg, ≥ 85 kg).

Paediatric population (<18 years)

The pharmacokinetics of epcoritamab in paediatric patients has not been established.

Immunogenicity

In EPCORE clinical study, 4 of 158 (2.5%) patients who were treated with EPKINLY at the full dose of 48 mg and evaluable for the presence of anti-drug antibodies (ADA) tested positive for anti-epcoritamab antibodies on treatment (two at cycle 2 day 22, one at cycle 1 day 22, and one at cycle 2 day 1) with titres of 1:320 or less. There was no evidence of an altered pharmacokinetic profile with anti-epcoritamab binding antibody development based on a population PK analysis. There are insufficient data to evaluate the effect of ADA on the safety or efficacy of epcoritamab.

5.3 Preclinical safety data

Genotoxicity

Genotoxicity studies have not been conducted with epcoritamab**.** As a large protein molecule, epcoritamab is not expected to interact with DNA or other chromosomal material.

Carcinogenicity

Carcinogenicity studies have not been conducted with epcoritamab.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium acetate trihydrate
Glacial acetic acid
Sorbitol
Polysorbate 80
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products and/or diluents except those listed in **Section 4.2 Dose and method of administration; Preparation and administration**.

6.3 Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store and transport at 2°C - 8°C (Refrigerate. Do not freeze).
Keep in the original carton to protect from light. Do not shake.
Refer to **Section 4.2 Dose and method of administration; Storage for diluted and prepared EPKINLY** for information on the storage for diluted and prepared EPKINLY.

6.5 Nature and contents of container

EPKINLY 4 mg/0.8 mL concentrate for solution for injection

Type I glass vial with bromobutyl rubber stopper and aluminum seal with plastic flip off cap. The vial stopper is not made with natural rubber latex. Pack size of 1 vial.

EPKINLY 48 mg/0.8 mL solution for injection

Type I glass vial with bromobutyl rubber stopper and aluminum seal with plastic flip off cap. The vial stopper is not made with natural rubber latex. Pack size of 1 vial.

6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 Physicochemical properties

Epcoritamab has a regular IgG1 structure and biochemical characteristics typical of human IgG1 and has an approximate molecular weight of 149 kDa.

CAS Number: 2134641-34-0

7. MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 – Prescription Only Medicine

8. SPONSOR

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

Australia

9. DATE OF FIRST APPROVAL

Pending

10. DATE OF REVISION

Not applicable

Summary table of changes

Section changed	Summary of new information
All	New Product Information