

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Fabhalta 200mg Hard Capsules  [Iptacopan 200 mg]	<p><b>INDICATION:</b> <u>Complement 3 glomerulopathy</u> FABHALTA is indicated for the treatment of adult patients with complement 3 glomerulopathy (C3G) in combination with a renin-angiotensin system (RAS) inhibitor, or in patients who are RAS-inhibitor intolerant, or for whom a RAS-inhibitor is contraindicated (see section 5.1).</p> <p><b>POSODOLOGY:</b> <u>Patients with C3G after kidney transplantation (recurrent C3G)</u> Diagnosis of recurrent C3G should be made based on histological C3 deposition in the glomeruli of the transplanted kidney. C3 deposition may be detected in a routine post-transplantation biopsy; otherwise, a biopsy should be performed when clinical signs indicate recurrent C3G. As done in study X2202 (see section 5.1), treatment with iptacopan can be started before the onset of clinical signs such as estimated glomerular filtration rate (eGFR) decrease or urine protein-to-creatinine ratio (UPCR) increase. There is limited experience with the use of iptacopan in patients with recurrent C3G after transplantation in clinical studies (see section 5.1).</p>	<p><b>NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.</b> Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.</p>
2.	BRUKINSA 80 mg capsules  [Zanubrutinib 80 mg]	<p><b>INDICATION:</b> BRUKINSA in combination with obinutuzumab is indicated for the treatment of adult patients with refractory or relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.</p> <p><b>POSODOLOGY:</b> Treatment with this medicinal product should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.</p>	<p><b>BEONE MEDICINES MALAYSIA SDN. BHD.</b> Anchor Office 4, Level 4, Uptown 7, Jalan SS21/39, Damansara Utama, 47400 Petaling Jaya, Selangor.</p>

**Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026**

***Products approved for additional indication (DCA 420 – 7 May 2026)***

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<p><u>Posology</u>                      The recommended total daily dose of zanubrutinib is 320 mg. The daily dose may be taken either once daily (four 80 mg capsules) or divided into two doses of 160 mg twice daily (two 80 mg capsules). Treatment with Brukinsa should be continued until disease progression or unacceptable toxicity.</p> <p>BRUKINSA in combination with Obinutuzumab                      Zanubrutinib must be administered orally before obinutuzumab infusion. The recommended dose is obinutuzumab 1,000 mg intravenously on Days 1, 8, and 15 of Cycle 1, and on Day 1 of every 28-day cycle from Cycles 2 to 6. At the discretion of the physician, obinutuzumab may be administered 100 mg on Day 1 and 900 mg on Day 2 of Cycle 1 instead of 1,000 mg on Day 1 of Cycle 1. Obinutuzumab maintenance (one infusion every two months for up to two years) may be prescribed. Refer to the obinutuzumab SmPC for additional dosing information, including premedication before each infusion.</p> <p><u>Dose modifications for adverse reactions</u>                      Recommended dose modifications of zanubrutinib for Grade 3 or greater adverse reactions are provided in Table 1.</p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)															
		<p>Table 1: Recommended dose modifications for adverse reactions</p> <table border="1"> <thead> <tr> <th data-bbox="506 352 907 472"><b>Adverse reaction</b></th> <th data-bbox="907 352 1229 472"><b>Adverse reaction occurrence</b></th> <th data-bbox="1229 352 1702 472"><b>Dose modification (starting dose: 320 mg once daily or 160 mg twice daily)</b></th> </tr> </thead> <tbody> <tr> <td data-bbox="506 472 907 667"> <p>≥Grade 3 non-haematological toxicities</p> <p>Grade 3 febrile neutropenia</p> </td> <td data-bbox="907 472 1229 667"> <p>First</p> </td> <td data-bbox="1229 472 1702 667"> <p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 320 mg once daily or 160 mg twice daily</p> </td> </tr> <tr> <td data-bbox="506 667 907 861"> <p>Grade 3 thrombocytopenia with significant bleeding</p> <p>Grade 4 neutropenia (lasting &gt; 10 consecutive days)</p> </td> <td data-bbox="907 667 1229 861"> <p>Second</p> </td> <td data-bbox="1229 667 1702 861"> <p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 160 mg once daily or 80 mg twice daily</p> </td> </tr> <tr> <td data-bbox="506 861 907 1018"> <p>Grade 4 thrombocytopenia (lasting &gt;10 consecutive days)</p> </td> <td data-bbox="907 861 1229 1018"> <p>Third</p> </td> <td data-bbox="1229 861 1702 1018"> <p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 80 mg once daily</p> </td> </tr> <tr> <td data-bbox="506 1018 907 1059"></td> <td data-bbox="907 1018 1229 1059"> <p>Fourth</p> </td> <td data-bbox="1229 1018 1702 1059"> <p>Discontinue BRUKINSA</p> </td> </tr> </tbody> </table> <p>Asymptomatic lymphocytosis should not be regarded as an adverse reaction, and these patients should continue taking BRUKINSA.</p> <p>For dose modification of obinutuzumab for adverse reactions, refer to the SmPC of obinutuzumab.</p> <p>Dose modifications for concomitant therapy</p> <p>Dose modifications for use with CYP3A inhibitors or inducers:</p>	<b>Adverse reaction</b>	<b>Adverse reaction occurrence</b>	<b>Dose modification (starting dose: 320 mg once daily or 160 mg twice daily)</b>	<p>≥Grade 3 non-haematological toxicities</p> <p>Grade 3 febrile neutropenia</p>	<p>First</p>	<p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 320 mg once daily or 160 mg twice daily</p>	<p>Grade 3 thrombocytopenia with significant bleeding</p> <p>Grade 4 neutropenia (lasting &gt; 10 consecutive days)</p>	<p>Second</p>	<p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 160 mg once daily or 80 mg twice daily</p>	<p>Grade 4 thrombocytopenia (lasting &gt;10 consecutive days)</p>	<p>Third</p>	<p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 80 mg once daily</p>		<p>Fourth</p>	<p>Discontinue BRUKINSA</p>	
<b>Adverse reaction</b>	<b>Adverse reaction occurrence</b>	<b>Dose modification (starting dose: 320 mg once daily or 160 mg twice daily)</b>																
<p>≥Grade 3 non-haematological toxicities</p> <p>Grade 3 febrile neutropenia</p>	<p>First</p>	<p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 320 mg once daily or 160 mg twice daily</p>																
<p>Grade 3 thrombocytopenia with significant bleeding</p> <p>Grade 4 neutropenia (lasting &gt; 10 consecutive days)</p>	<p>Second</p>	<p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 160 mg once daily or 80 mg twice daily</p>																
<p>Grade 4 thrombocytopenia (lasting &gt;10 consecutive days)</p>	<p>Third</p>	<p>Interrupt BRUKINSA</p> <p>Once toxicity has resolved to ≤Grade 1 or baseline: Resume at 80 mg once daily</p>																
	<p>Fourth</p>	<p>Discontinue BRUKINSA</p>																

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)														
		<p>Table 2: Recommended dose modifications when co-administered with other medicinal products</p> <table border="1" data-bbox="506 389 1722 940"> <thead> <tr> <th data-bbox="506 389 674 469"><b>CYP3A</b></th> <th data-bbox="674 389 1420 469"><b>Co-administered medicinal product</b></th> <th data-bbox="1420 389 1722 469"><b>Recommended dose</b></th> </tr> </thead> <tbody> <tr> <td data-bbox="506 469 674 587"><i>Inhibition</i></td> <td data-bbox="674 469 1420 587"><i>Strong CYP3A inhibitor (e.g., posaconazole, voriconazole, ketoconazole, itraconazole, clarithromycin, indinavir, lopinavir, ritonavir, telaprevir)</i></td> <td data-bbox="1420 469 1722 587"><i>80 mg once daily</i></td> </tr> <tr> <td data-bbox="506 587 674 746"></td> <td data-bbox="674 587 1420 746"><i>Moderate CYP3A inhibitor (e.g., erythromycin, ciprofloxacin, diltiazem, dronedarone, fluconazole, verapamil, aprepitant, imatinib, grapefruit juice, Seville oranges)</i></td> <td data-bbox="1420 587 1722 746"><i>80 mg twice daily</i></td> </tr> <tr> <td data-bbox="506 746 674 940"><i>Induction</i></td> <td data-bbox="674 746 1420 940"><i>Strong CYP3A inducer (e.g., carbamazepine, phenytoin, rifampin, St. John's wort)</i></td> <td data-bbox="1420 746 1722 940" rowspan="2"><i>Avoid concomitant use; Consider alternative agents with less CYP3A induction</i></td> </tr> <tr> <td data-bbox="506 940 674 940"></td> <td data-bbox="674 940 1420 940"><i>Moderate CYP3A inducer (e.g., bosentan, efavirenz, etravirine, modafinil, nafcillin)</i></td> </tr> </tbody> </table> <p data-bbox="506 1023 674 1054"><u>Missed dose</u></p> <p data-bbox="506 1062 1722 1129">A double dose should not be taken to make up for a forgotten dose. If a dose is not taken at the scheduled time, the next dose should be taken according to the normal schedule.</p> <p data-bbox="506 1177 763 1209"><u>Special populations</u></p> <p data-bbox="506 1217 600 1249"><u>Elderly</u></p> <p data-bbox="506 1257 1503 1289">No specific dose adjustment is required for elderly patients (aged ≥65 years).</p> <p data-bbox="506 1337 741 1369"><u>Renal impairment</u></p> <p data-bbox="506 1377 1722 1409">No dose modification is recommended in patients with mild to moderate renal impairment</p>	<b>CYP3A</b>	<b>Co-administered medicinal product</b>	<b>Recommended dose</b>	<i>Inhibition</i>	<i>Strong CYP3A inhibitor (e.g., posaconazole, voriconazole, ketoconazole, itraconazole, clarithromycin, indinavir, lopinavir, ritonavir, telaprevir)</i>	<i>80 mg once daily</i>		<i>Moderate CYP3A inhibitor (e.g., erythromycin, ciprofloxacin, diltiazem, dronedarone, fluconazole, verapamil, aprepitant, imatinib, grapefruit juice, Seville oranges)</i>	<i>80 mg twice daily</i>	<i>Induction</i>	<i>Strong CYP3A inducer (e.g., carbamazepine, phenytoin, rifampin, St. John's wort)</i>	<i>Avoid concomitant use; Consider alternative agents with less CYP3A induction</i>		<i>Moderate CYP3A inducer (e.g., bosentan, efavirenz, etravirine, modafinil, nafcillin)</i>	
<b>CYP3A</b>	<b>Co-administered medicinal product</b>	<b>Recommended dose</b>															
<i>Inhibition</i>	<i>Strong CYP3A inhibitor (e.g., posaconazole, voriconazole, ketoconazole, itraconazole, clarithromycin, indinavir, lopinavir, ritonavir, telaprevir)</i>	<i>80 mg once daily</i>															
	<i>Moderate CYP3A inhibitor (e.g., erythromycin, ciprofloxacin, diltiazem, dronedarone, fluconazole, verapamil, aprepitant, imatinib, grapefruit juice, Seville oranges)</i>	<i>80 mg twice daily</i>															
<i>Induction</i>	<i>Strong CYP3A inducer (e.g., carbamazepine, phenytoin, rifampin, St. John's wort)</i>	<i>Avoid concomitant use; Consider alternative agents with less CYP3A induction</i>															
	<i>Moderate CYP3A inducer (e.g., bosentan, efavirenz, etravirine, modafinil, nafcillin)</i>																

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<p>(creatinine clearance (CrCl) <math>\geq</math>30 mL/min, estimated by Cockcroft-Gault). There is limited data on patients with severe renal impairment and end-stage renal disease (n=5). Patients with severe renal impairment (CrCl &lt;30 mL/min) or on dialysis should be monitored for adverse reactions.</p> <p><u>Hepatic impairment</u> Dose modifications are not needed in patients with mild (Child-Pugh class A) or moderate hepatic impairment (Child-Pugh class B). Patients with mild or moderate hepatic impairment were treated in BRUKINSA clinical studies. The recommended dose of BRUKINSA for patients with severe hepatic impairment (Child-Pugh class C) is 80 mg orally twice daily. The safety of BRUKINSA has not been evaluated in patients with severe hepatic impairment. Monitor these patients closely for adverse events of BRUKINSA.</p> <p><u>Paediatric population</u> The safety and efficacy of BRUKINSA in children and adolescents below 18 years of age have not been established. No data are available.</p> <p><u>Method of administration</u> BRUKINSA is for oral use. The hard capsules can be taken with or without food. Patients should be instructed to swallow the capsules whole with water, and not to open, break or chew the capsules.</p>	
3.	<p>Firialta Film Coated Tablet 10mg</p> <p>[Finerenone micronised 10 mg]</p> <p>Firialta Film</p>	<p><b>INDICATION:</b> Firialta is indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adults with heart failure and left ventricular ejection fraction (LVEF) <math>\geq</math>40%.</p>	<p><b>BAYER CO. (MALAYSIA) SDN. BHD.</b> 25-03 &amp; 25-04, Level 25, Imazium, No. 8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.</p>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
	<p>Coated Tablet 20mg</p> <p>[Finerenone micronized 20mg]</p>	<p><b>POSODOLOGY:</b></p> <p><b>Initiation of treatment</b></p> <p><b>Serum Potassium Limits</b></p> <p><u>Heart Failure (LVEF ≥40%)</u></p> <p>In patients with heart failure (LVEF ≥40%), initiation of Firalta treatment is recommended when serum potassium ≤5.0 mmol/L.</p> <p><b>Starting Dose for All Indications</b></p> <p>Measure estimated glomerular filtration rate (eGFR) to determine the starting dose. The starting dose of Firalta is:</p> <ul style="list-style-type: none"> <li>• 20 mg once daily if eGFR ≥ 60 mL/min/1.73 m<sup>2</sup></li> <li>• 10 mg once daily if eGFR ≥ 25 to &lt; 60 mL/min/1.73 m<sup>2</sup></li> </ul> <p>Initiation of Firalta treatment is not recommended in patients with eGFR &lt; 25 mL/min/1.73 m<sup>2</sup> as clinical experience is limited.</p> <p><b>Target dose</b></p> <p><u>Heart Failure (LVEF ≥40%)</u></p> <p>For patients with heart failure (LVEF ≥40%), the recommended target dose of Firalta depends on renal function (eGFR) at initiation of Firalta treatment (see Table 2):</p> <ul style="list-style-type: none"> <li>• 40 mg once daily if eGFR ≥60 mL/min/1.73m<sup>2</sup></li> <li>• 20 mg once daily if eGFR ≥25 to &lt;60 mL/min/1.73m<sup>2</sup></li> </ul> <p><b>Continuation of treatment</b></p> <p>Four weeks after initiation or re-start or dose adjustment of Firalta treatment, remeasure serum potassium and eGFR. See Table 2 to determine continuation of Firalta treatment and dose adjustment.</p> <p>Thereafter, remeasure serum potassium periodically and as needed based on patient</p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)										
		<p>characteristics and serum potassium levels.</p> <p>Table 2: Continuation of Firalta Treatment and Dose Adjustment for Patients with Heart Failure (LVEF <math>\geq</math>40%)</p> <table border="1" data-bbox="512 469 1700 1248"> <thead> <tr> <th data-bbox="512 469 837 571"><b>Serum Potassium (mmol/L)</b></th> <th data-bbox="837 469 1700 571"><b>Firalta Dose (after 4 weeks and thereafter)</b></th> </tr> </thead> <tbody> <tr> <td data-bbox="512 571 837 828">&lt;5.0</td> <td data-bbox="837 571 1700 828"> <p>If on 10 mg once daily, increase to 20 mg once daily.*</p> <p>If on 20 mg once daily, either maintain dose, or when eGFR <math>\geq</math>60 mL/min/1.73m<sup>2</sup> at treatment initiation, increase to 40 mg once daily.*</p> <p>Maintain target dose of 40 mg once daily.</p> </td> </tr> <tr> <td data-bbox="512 828 837 887">5.0 to &lt;5.5</td> <td data-bbox="837 828 1700 887">Maintain dose.</td> </tr> <tr> <td data-bbox="512 887 837 1042">5.5 to &lt;6.0</td> <td data-bbox="837 887 1700 1042"> <p>Decrease to next lower dose.</p> <p>Withhold Firalta if on 10 mg once daily.</p> <p>Restart at 10 mg once daily if serum potassium &lt;5.5 mmol/L.</p> </td> </tr> <tr> <td data-bbox="512 1042 837 1145"><math>\geq</math>6.0</td> <td data-bbox="837 1042 1700 1145"> <p>Withhold Firalta.</p> <p>Restart at 10 mg once daily if serum potassium &lt;5.5 mmol/L.**</p> </td> </tr> </tbody> </table> <p>*if eGFR has not decreased &gt;30% compared to prior measurement.</p> <p>**If repeated measurements <math>\geq</math>5.5 mmol/L, restart at 10 mg once daily when &lt;5.0 mmol/L.</p> <p><b>Maximum daily dose</b> Heart Failure (LVEF <math>\geq</math>40%) For patients with heart failure (LVEF <math>\geq</math>40%), the maximum daily dose of Firalta is 40 mg.</p>	<b>Serum Potassium (mmol/L)</b>	<b>Firalta Dose (after 4 weeks and thereafter)</b>	<5.0	<p>If on 10 mg once daily, increase to 20 mg once daily.*</p> <p>If on 20 mg once daily, either maintain dose, or when eGFR <math>\geq</math>60 mL/min/1.73m<sup>2</sup> at treatment initiation, increase to 40 mg once daily.*</p> <p>Maintain target dose of 40 mg once daily.</p>	5.0 to <5.5	Maintain dose.	5.5 to <6.0	<p>Decrease to next lower dose.</p> <p>Withhold Firalta if on 10 mg once daily.</p> <p>Restart at 10 mg once daily if serum potassium &lt;5.5 mmol/L.</p>	$\geq$ 6.0	<p>Withhold Firalta.</p> <p>Restart at 10 mg once daily if serum potassium &lt;5.5 mmol/L.**</p>	
<b>Serum Potassium (mmol/L)</b>	<b>Firalta Dose (after 4 weeks and thereafter)</b>												
<5.0	<p>If on 10 mg once daily, increase to 20 mg once daily.*</p> <p>If on 20 mg once daily, either maintain dose, or when eGFR <math>\geq</math>60 mL/min/1.73m<sup>2</sup> at treatment initiation, increase to 40 mg once daily.*</p> <p>Maintain target dose of 40 mg once daily.</p>												
5.0 to <5.5	Maintain dose.												
5.5 to <6.0	<p>Decrease to next lower dose.</p> <p>Withhold Firalta if on 10 mg once daily.</p> <p>Restart at 10 mg once daily if serum potassium &lt;5.5 mmol/L.</p>												
$\geq$ 6.0	<p>Withhold Firalta.</p> <p>Restart at 10 mg once daily if serum potassium &lt;5.5 mmol/L.**</p>												

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Keytruda 100mg Solution for Infusion  [Pembrolizumab 25mg/ml]	<p><b>INDICATION:</b> <u>Malignant Pleural Mesothelioma</u></p> <p>KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adults with unresectable non-epithelioid malignant pleural mesothelioma (MPM).</p>	<p><b>MERCK SHARP &amp; DOHME (MALAYSIA) SDN. BHD.</b></p> <p>Lot No. B-22-1 &amp; B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.</p>
5.	Keytruda 100mg Solution for Infusion  [Pembrolizumab 25mg/ml]	<p><b>INDICATION:</b> <u>Head and Neck Cancer</u></p> <p>KEYTRUDA as monotherapy is indicated for the treatment of resectable locally advanced head and neck squamous cell carcinoma as neoadjuvant treatment, continued as adjuvant treatment in combination with radiation therapy with or without concomitant cisplatin and then as monotherapy in adults whose tumours express PD-L1 [Combined Positive Score (CPS) <math>\geq</math> 1].</p> <p><b>POSODOLOGY:</b> For the neoadjuvant and adjuvant treatment of resectable locally advanced HNSCC, patients should be treated with neoadjuvant KEYTRUDA as monotherapy for 2 doses of 200 mg every 3 weeks or 1 dose of 400 mg or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA in combination with radiation with or without concomitant cisplatin for 3 doses of 200 mg every 3 weeks or 2 doses of 400 mg every 6 weeks followed by KEYTRUDA as monotherapy for 12 doses of 200 mg every 3 weeks or 6 doses of 400 mg every 6 weeks or until disease recurrence or</p>	<p><b>MERCK SHARP &amp; DOHME (MALAYSIA) SDN. BHD.</b></p> <p>Lot No. B-22-1 &amp; B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.</p>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<p>unacceptable toxicity. Patients who experience disease progression that precludes definitive surgery or unacceptable toxicity related to KEYTRUDA monotherapy as neoadjuvant treatment should not receive KEYTRUDA in combination with radiation with or without concomitant cisplatin as adjuvant treatment.</p>	
6.	<p>Epkinly Concentrate for Solution for Injection 4mg/0.8ml</p> <p>[Epcoritamab 5mg/mL]</p> <p>Epkinly Solution for Injection 48mg/0.8ml</p> <p>[Epcoritamab 60mg/mL]</p>	<p><b>INDICATION:</b> Epkinly as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.</p> <p>This indication is approved conditionally which is based on response rate and durability of response. Continued approval for this indication may be based on the outcome of clinical benefit in a confirmatory trial.</p> <p><b>POSODOLOGY:</b> Epkinly must only be administered under the supervision of a healthcare professional qualified in the use of anti-cancer therapy. At least 1 dose of tocilizumab for use in the event of CRS should be available prior to epcoritamab administration for Cycle 1. Access to an additional dose of tocilizumab within 8 hours of use of the previous tocilizumab dose should be available.</p> <p><u>Posology</u> Recommended pre-medication and dose schedule Epkinly should be administered according to the following step-up dose schedule in 28-day cycles which is outlined in Table 1 for patients with diffuse large B-cell lymphoma and Table 2 for patients with follicular lymphoma.</p>	<p><b>ABBVIE SDN BHD</b> 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf &amp; Country Resort, 47410 Petaling Jaya, Selangor.</p>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)																														
		<p>Table 1: Epkinly 2-step step-up dose schedule for patients with diffuse large B-cell lymphoma</p> <table border="1"> <thead> <tr> <th data-bbox="524 352 804 427"><i>Dosing schedule</i></th> <th data-bbox="804 352 1086 427"><i>Cycle of treatment</i></th> <th data-bbox="1086 352 1332 427"><i>Days</i></th> <th data-bbox="1332 352 1711 427"><i>Epcoritamab dose (mg)<sup>a</sup></i></th> </tr> </thead> <tbody> <tr> <td data-bbox="524 427 804 727" rowspan="4"><i>Weekly</i></td> <td data-bbox="804 427 1086 727" rowspan="4"><i>Cycle 1</i></td> <td data-bbox="1086 427 1332 502">1</td> <td data-bbox="1332 427 1711 502"><i>0.16 mg (Step-up dose 1)</i></td> </tr> <tr> <td data-bbox="1086 502 1332 577">8</td> <td data-bbox="1332 502 1711 577"><i>0.8 mg (Step-up dose 2)</i></td> </tr> <tr> <td data-bbox="1086 577 1332 652">15</td> <td data-bbox="1332 577 1711 652"><i>48 mg (First full dose)</i></td> </tr> <tr> <td data-bbox="1086 652 1332 727">22</td> <td data-bbox="1332 652 1711 727"><i>48 mg</i></td> </tr> <tr> <td data-bbox="524 727 804 802"><i>Weekly</i></td> <td data-bbox="804 727 1086 802"><i>Cycles 2 - 3</i></td> <td data-bbox="1086 727 1332 802"><i>1, 8, 15, 22</i></td> <td data-bbox="1332 727 1711 802"><i>48 mg</i></td> </tr> <tr> <td data-bbox="524 802 804 877"><i>Every two weeks</i></td> <td data-bbox="804 802 1086 877"><i>Cycles 4 - 9</i></td> <td data-bbox="1086 802 1332 877"><i>1, 15</i></td> <td data-bbox="1332 802 1711 877"><i>48 mg</i></td> </tr> <tr> <td data-bbox="524 877 804 952"><i>Every four weeks</i></td> <td data-bbox="804 877 1086 952"><i>Cycles 10 +</i></td> <td data-bbox="1086 877 1332 952"><i>1</i></td> <td data-bbox="1332 877 1711 952"><i>48 mg</i></td> </tr> <tr> <td colspan="4" data-bbox="524 952 1711 1027"><i><sup>a</sup>0.16 mg is a priming dose, 0.8 mg is an intermediate dose and 48 mg is a full dose.</i></td> </tr> </tbody> </table>	<i>Dosing schedule</i>	<i>Cycle of treatment</i>	<i>Days</i>	<i>Epcoritamab dose (mg)<sup>a</sup></i>	<i>Weekly</i>	<i>Cycle 1</i>	1	<i>0.16 mg (Step-up dose 1)</i>	8	<i>0.8 mg (Step-up dose 2)</i>	15	<i>48 mg (First full dose)</i>	22	<i>48 mg</i>	<i>Weekly</i>	<i>Cycles 2 - 3</i>	<i>1, 8, 15, 22</i>	<i>48 mg</i>	<i>Every two weeks</i>	<i>Cycles 4 - 9</i>	<i>1, 15</i>	<i>48 mg</i>	<i>Every four weeks</i>	<i>Cycles 10 +</i>	<i>1</i>	<i>48 mg</i>	<i><sup>a</sup>0.16 mg is a priming dose, 0.8 mg is an intermediate dose and 48 mg is a full dose.</i>				
<i>Dosing schedule</i>	<i>Cycle of treatment</i>	<i>Days</i>	<i>Epcoritamab dose (mg)<sup>a</sup></i>																														
<i>Weekly</i>	<i>Cycle 1</i>	1	<i>0.16 mg (Step-up dose 1)</i>																														
		8	<i>0.8 mg (Step-up dose 2)</i>																														
		15	<i>48 mg (First full dose)</i>																														
		22	<i>48 mg</i>																														
<i>Weekly</i>	<i>Cycles 2 - 3</i>	<i>1, 8, 15, 22</i>	<i>48 mg</i>																														
<i>Every two weeks</i>	<i>Cycles 4 - 9</i>	<i>1, 15</i>	<i>48 mg</i>																														
<i>Every four weeks</i>	<i>Cycles 10 +</i>	<i>1</i>	<i>48 mg</i>																														
<i><sup>a</sup>0.16 mg is a priming dose, 0.8 mg is an intermediate dose and 48 mg is a full dose.</i>																																	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)																																		
		<p>Table 2: Epcinly 3-step step-up dose schedule for patients with follicular lymphoma</p> <table border="1"> <thead> <tr> <th data-bbox="524 352 786 403">Dosing schedule</th> <th data-bbox="786 352 1106 403">Cycle of treatment</th> <th data-bbox="1106 352 1335 403">Days</th> <th data-bbox="1335 352 1711 403">Epcoritamab dose (mg)<sup>a</sup></th> </tr> </thead> <tbody> <tr> <td data-bbox="524 403 786 619" rowspan="4">Weekly</td> <td data-bbox="786 403 1106 619" rowspan="4">Cycle 1</td> <td data-bbox="1106 403 1335 459">1</td> <td data-bbox="1335 403 1711 459">0.16 mg (Step-up dose 1)</td> </tr> <tr> <td data-bbox="1106 459 1335 515">8</td> <td data-bbox="1335 459 1711 515">0.8 mg (Step-up dose 2)</td> </tr> <tr> <td data-bbox="1106 515 1335 571">15</td> <td data-bbox="1335 515 1711 571"><b>3 mg (Step-up dose 3)</b></td> </tr> <tr> <td data-bbox="1106 571 1335 619">22</td> <td data-bbox="1335 571 1711 619">48 mg (First full dose)</td> </tr> <tr> <td data-bbox="524 619 786 675">Weekly</td> <td data-bbox="786 619 1106 675">Cycles 2 - 3</td> <td data-bbox="1106 619 1335 675">1, 8, 15, 22</td> <td data-bbox="1335 619 1711 675">48 mg</td> </tr> <tr> <td data-bbox="524 675 786 730">Every two weeks</td> <td data-bbox="786 675 1106 730">Cycles 4 - 9</td> <td data-bbox="1106 675 1335 730">1, 15</td> <td data-bbox="1335 675 1711 730">48 mg</td> </tr> <tr> <td data-bbox="524 730 786 786">Every four weeks</td> <td data-bbox="786 730 1106 786">Cycles 10 +</td> <td data-bbox="1106 730 1335 786">1</td> <td data-bbox="1335 730 1711 786">48 mg</td> </tr> </tbody> </table> <p><sup>a</sup>0.16 mg is a priming dose, 0.8 mg is an intermediate dose, <b>3 mg is a second intermediate dose</b> and 48 mg is a full dose.</p> <p>Epcinly should be administered until disease progression or unacceptable toxicity.</p> <p>Details on recommended pre-medication for cytokine release syndrome (CRS) are shown in Table 3.</p> <p>Table 3: Epcoritamab Premedications</p> <table border="1"> <thead> <tr> <th data-bbox="524 1182 674 1281">Cycle</th> <th data-bbox="674 1182 958 1281">Patient requiring premedication</th> <th data-bbox="958 1182 1267 1281">Premedication</th> <th data-bbox="1267 1182 1702 1281">Administration</th> </tr> </thead> <tbody> <tr> <td data-bbox="524 1281 674 1430">Cycle 1</td> <td data-bbox="674 1281 958 1430">All patients</td> <td data-bbox="958 1281 1267 1430">Dexamethasone<sup>b</sup> (15 mg oral or intravenous) or</td> <td data-bbox="1267 1281 1702 1430"> <ul style="list-style-type: none"> <li>30-120 minutes prior to each weekly administration of</li> </ul> </td> </tr> </tbody> </table>	Dosing schedule	Cycle of treatment	Days	Epcoritamab dose (mg) <sup>a</sup>	Weekly	Cycle 1	1	0.16 mg (Step-up dose 1)	8	0.8 mg (Step-up dose 2)	15	<b>3 mg (Step-up dose 3)</b>	22	48 mg (First full dose)	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	Cycle	Patient requiring premedication	Premedication	Administration	Cycle 1	All patients	Dexamethasone <sup>b</sup> (15 mg oral or intravenous) or	<ul style="list-style-type: none"> <li>30-120 minutes prior to each weekly administration of</li> </ul>	
Dosing schedule	Cycle of treatment	Days	Epcoritamab dose (mg) <sup>a</sup>																																		
Weekly	Cycle 1	1	0.16 mg (Step-up dose 1)																																		
		8	0.8 mg (Step-up dose 2)																																		
		15	<b>3 mg (Step-up dose 3)</b>																																		
		22	48 mg (First full dose)																																		
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																																		
Cycle	Patient requiring premedication	Premedication	Administration																																		
Cycle 1	All patients	Dexamethasone <sup>b</sup> (15 mg oral or intravenous) or	<ul style="list-style-type: none"> <li>30-120 minutes prior to each weekly administration of</li> </ul>																																		

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)	
				<p><i>Prednisolone (100 mg oral or IV) or equivalent</i></p>	<p><i>epcoritamab</i></p> <ul style="list-style-type: none"> <li>• <i>And for three consecutive days following each weekly administration of epcoritamab in Cycle 1</i></li> </ul>	
				<ul style="list-style-type: none"> <li>• <i>Diphenhydramine (50 mg oral or IV) or equivalent</i></li> <li>• <i>Paracetamol (650 to 1,000 mg oral)</i></li> </ul>	<p><i>30-120 minutes prior to each weekly administration of epcoritamab</i></p>	
		<p><b>Cycle 2 and beyond</b></p>	<p><i>Patients who experienced Grade 2 or 3<sup>a</sup> CRS with previous dose</i></p>	<p><i>Dexamethasone<sup>b</sup> (15 mg oral or intravenous) or Prednisolone (100 mg oral or IV) or equivalent</i></p>	<ul style="list-style-type: none"> <li>• <i>30-120 minutes prior to next administration of epcoritamab after a grade 2 or 3<sup>a</sup> CRS event</i></li> <li>• <i>And for three consecutive days</i></li> </ul>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication				Product Registration Holder (PRH)
					<p><i>following the next administration of epcoritamab until epcoritamab is given without subsequent any grade of CRS</i></p>	
<p><i><sup>a</sup> Patients will be permanently discontinued from epcoritamab after a Grade 4 CRS event.</i></p> <p><i><sup>b</sup> Dexamethasone is the preferred corticosteroid for CRS prophylaxis based on the GCT3013-01 Optimisation study</i></p>						
<p>Prophylaxis against Pneumocystis jirovecii pneumonia (PCP) and herpes virus infections is strongly recommended especially during concurrent use of steroids.</p>						
<p>Epkinly should be administered to adequately hydrated patients.</p>						
<p>It is strongly recommended that all patients adhere to the following fluid guidelines during Cycle 1, unless medically contraindicated:</p> <ul style="list-style-type: none"> <li>● 2-3 L of fluid intake during the 24 hours prior to each epcoritamab administration</li> <li>● Hold antihypertensive medications for 24 hours prior to each epcoritamab administration</li> <li>● Administer 500 ml isotonic intravenous (IV) fluids on the day of epcoritamab prior to dose administration; AND</li> </ul>						

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<ul style="list-style-type: none"> <li>• 2-3 L of fluid intake during the 24 hours following each epcoritamab administration.</li> </ul> <p>Patients at an increased risk for clinical tumour lysis syndrome (CTLS) are recommended to receive hydration and prophylactic treatment with a uric acid lowering agent.</p> <p>Patients should be monitored for signs and symptoms of CRS and/or immune effector cell-associated neurotoxicity syndrome (ICANS) and managed per current practice guidelines following epcoritamab administration. Patients should be counselled 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 Warnings and Precautions section).</p> <p>Patients with DLBCL should be hospitalised for 24 hours after administration of the Cycle 1 Day 15 dose of 48 mg to monitor for signs and symptoms of CRS and/or ICANS.</p> <p><u>Dosage Modifications and Management of Adverse Reactions</u></p> <p>Cytokine Release Syndrome (CRS)</p> <p>Patients treated with epcoritamab 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 4. Patients who experience CRS should be monitored more frequently during next scheduled epcoritamab administration.</p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)						
		<p><b>Table 4 CRS Grading and Management Guidance</b></p> <table border="1"> <thead> <tr> <th data-bbox="524 363 891 464"><i>Grade<sup>a</sup></i></th> <th data-bbox="891 363 1303 464"><i>Recommended Therapy</i></th> <th data-bbox="1303 363 1700 464"><i>Epcoritamab Dose Modification</i></th> </tr> </thead> <tbody> <tr> <td data-bbox="524 464 891 1276"> <p><b>Grade 1</b></p> <ul style="list-style-type: none"> <li><i>Fever (temperature ≥ 38°C)</i></li> </ul> </td> <td data-bbox="891 464 1303 1276"> <p><i>Provide supportive care such as antipyretics and intravenous hydration</i></p> <p><i>Dexamethasone<sup>b</sup> may be initiated</i></p> <p><i>In cases of advanced age, high tumour burden, circulating tumour cells, fever refractory to antipyretics</i></p> <ul style="list-style-type: none"> <li><i>Anti-cytokine therapy, tocilizumab<sup>d</sup>, should be considered</i></li> </ul> <p><i>For CRS with concurrent ICANS refer to <b>Table 5</b></i></p> </td> <td data-bbox="1303 464 1700 1276"> <p><i>Hold epcoritamab until resolution of CRS event.</i></p> </td> </tr> </tbody> </table>	<i>Grade<sup>a</sup></i>	<i>Recommended Therapy</i>	<i>Epcoritamab Dose Modification</i>	<p><b>Grade 1</b></p> <ul style="list-style-type: none"> <li><i>Fever (temperature ≥ 38°C)</i></li> </ul>	<p><i>Provide supportive care such as antipyretics and intravenous hydration</i></p> <p><i>Dexamethasone<sup>b</sup> may be initiated</i></p> <p><i>In cases of advanced age, high tumour burden, circulating tumour cells, fever refractory to antipyretics</i></p> <ul style="list-style-type: none"> <li><i>Anti-cytokine therapy, tocilizumab<sup>d</sup>, should be considered</i></li> </ul> <p><i>For CRS with concurrent ICANS refer to <b>Table 5</b></i></p>	<p><i>Hold epcoritamab until resolution of CRS event.</i></p>	
<i>Grade<sup>a</sup></i>	<i>Recommended Therapy</i>	<i>Epcoritamab Dose Modification</i>							
<p><b>Grade 1</b></p> <ul style="list-style-type: none"> <li><i>Fever (temperature ≥ 38°C)</i></li> </ul>	<p><i>Provide supportive care such as antipyretics and intravenous hydration</i></p> <p><i>Dexamethasone<sup>b</sup> may be initiated</i></p> <p><i>In cases of advanced age, high tumour burden, circulating tumour cells, fever refractory to antipyretics</i></p> <ul style="list-style-type: none"> <li><i>Anti-cytokine therapy, tocilizumab<sup>d</sup>, should be considered</i></li> </ul> <p><i>For CRS with concurrent ICANS refer to <b>Table 5</b></i></p>	<p><i>Hold epcoritamab until resolution of CRS event.</i></p>							

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		<p><b>Grade 2</b></p> <ul style="list-style-type: none"> <li>Fever (temperature <math>\geq</math> 38°C)</li> </ul> <p>And</p> <ul style="list-style-type: none"> <li>Hypotension not requiring vasopressors.</li> </ul> <p>and/or</p> <p>Hypoxia requiring low-flow oxygen<sup>e</sup> by nasal cannula or blow-by</p>	<p>Provide supportive care such as antipyretics and intravenous hydration</p> <p>Dexamethasone<sup>b</sup> should be considered</p> <p>Anti-cytokine therapy, tocilizumab<sup>d</sup>, is recommended</p> <p>If CRS is refractory to dexamethasone and tocilizumab:</p> <ul style="list-style-type: none"> <li>Alternative immunosuppressants<sup>g</sup> and methylprednisolone 1 000 mg/day intravenously should be administered until clinical improvement</li> </ul>	<p>Hold epcoritamab until resolution of CRS event.</p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
			<p><i>For CRS with concurrent ICANS refer to <b>Table 5</b></i></p>		
		<p><b>Grade 3</b></p> <ul style="list-style-type: none"> <li>● <i>Fever (temperature ≥ 38 °C)</i></li> </ul> <p><i>and</i></p> <ul style="list-style-type: none"> <li>● <i>Hypotension requiring a vasopressor with or without vasopressin</i></li> </ul> <p><i>and/or</i></p> <ul style="list-style-type: none"> <li>● <i>Hypoxia requiring high-flow oxygen<sup>f</sup> by nasal cannula,</i></li> </ul>	<p><i>Provide supportive care such as antipyretics and intravenous hydration</i></p> <p><i>Dexamethasone<sup>c</sup> should be administered</i></p> <p><i>Anti-cytokine therapy, tocilizumab<sup>d</sup>, is recommended</i></p> <p><i>If CRS is refractory to dexamethasone and tocilizumab:</i></p> <ul style="list-style-type: none"> <li>● <i>Alternative immunosuppressants<sup>g</sup></i></li> </ul>	<p><i>Hold epcoritamab until resolution of CRS event.</i></p> <p><i>In the event of Grade 3 CRS lasting longer than 72 hours, epcoritamab should be discontinued</i></p> <p><i>If more than 2 separate events of Grade 3 CRS, even if each event resolved to Grade 2 within 72 hours, epcoritamab should be discontinued</i></p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		<p><i>facemask, non-rebreather mask, or venturi mask</i></p>	<p><i>and methylprednisolone 1 000 mg/day intravenously should be administered until clinical improvement For CRS with concurrent ICANS refer to <b>Table 5</b></i></p>		
		<p><b>Grade 4</b></p> <ul style="list-style-type: none"> <li>● <i>Fever (temperature ≥ 38 °C)</i></li> </ul> <p><i>and</i></p> <ul style="list-style-type: none"> <li>● <i>Hypotension requiring ≥ 2 vasopressors (excluding vasopressin)</i></li> </ul> <p><i>and/or</i></p> <ul style="list-style-type: none"> <li>● <i>Hypoxia requiring positive pressure</i></li> </ul>	<p><i>Provide supportive care such as antipyretics and intravenous hydration</i></p> <p><i>Dexamethasone<sup>c</sup> should be administered</i></p> <p><i>Anti-cytokine therapy, tocilizumab<sup>d</sup> is recommended</i></p> <p><i>If CRS is refractory to dexamethasone and tocilizumab:</i></p> <ul style="list-style-type: none"> <li>● <i>Alternative immunosuppressants<sup>g</sup></i></li> </ul>	<p><i>Permanently discontinue epcoritamab</i></p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		<p><i>ventilation (e.g., CPAP, BiPAP, intubation and mechanical ventilation)</i></p>	<p><i>and methylprednisolone 1 000 mg/day intravenously should be administered until clinical improvement For CRS with concurrent ICANS refer to <b>Table 5</b></i></p>		
<p><sup>a</sup>CRS graded according to ASTCT consensus criteria  <sup>b</sup>Dexamethasone should be administered at 10-20 mg per day (or equivalent)  <sup>c</sup>Dexamethasone should be administered at 10-20 mg intravenously every 6 hours  <sup>d</sup>Tocilizumab 8 mg/kg intravenously 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  <sup>e</sup>Low-flow oxygen is defined as oxygen delivered at &lt; 6 L/minute  <sup>f</sup>High-flow oxygen is defined as oxygen delivered at ≥ 6 L/minute  <sup>g</sup>Riegler L et al. (2019)</p> <p>Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS)</p> <p>Patients should be monitored for signs and symptoms of ICANS. Other causes of neurologic</p>					

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)						
		<p>symptoms should be ruled out. If ICANS is suspected, manage according to the recommendations in Table 5.</p> <p><b>Table 5 ICANS Grading and Management Guidance</b></p> <table border="1" data-bbox="524 515 1704 1428"> <thead> <tr> <th data-bbox="524 515 844 619"><b>Grade<sup>a</sup></b></th> <th data-bbox="844 515 1352 619"><b>Recommended Therapy</b></th> <th data-bbox="1352 515 1704 619"><b>Epcoritamab Dose Modification</b></th> </tr> </thead> <tbody> <tr> <td data-bbox="524 619 844 1428"> <b>Grade 1</b>                      ICE score<sup>c</sup> 7-9<sup>b</sup>                      or, depressed level of consciousness<sup>b</sup>:                      awakens spontaneously                 </td> <td data-bbox="844 619 1352 1428">                     Treatment with dexamethasone<sup>d</sup>                       Consider non-sedating anti-seizure medicinal products (e.g., levetiracetam) until resolution of ICANS                       No concurrent CRS:                      • Anti-cytokine therapy not recommended                       For ICANS with concurrent CRS:                      • Treatment with dexamethasone<sup>d</sup>                      • Choose immunosuppressant alternatives<sup>e</sup> to tocilizumab, if possible                 </td> <td data-bbox="1352 619 1704 1428">                     Hold epcoritamab until resolution of event.                 </td> </tr> </tbody> </table>	<b>Grade<sup>a</sup></b>	<b>Recommended Therapy</b>	<b>Epcoritamab Dose Modification</b>	<b>Grade 1</b> ICE score <sup>c</sup> 7-9 <sup>b</sup> or, depressed level of consciousness <sup>b</sup> : awakens spontaneously	Treatment with dexamethasone <sup>d</sup>  Consider non-sedating anti-seizure medicinal products (e.g., levetiracetam) until resolution of ICANS  No concurrent CRS: • Anti-cytokine therapy not recommended  For ICANS with concurrent CRS: • Treatment with dexamethasone <sup>d</sup> • Choose immunosuppressant alternatives <sup>e</sup> to tocilizumab, if possible	Hold epcoritamab until resolution of event.	
<b>Grade<sup>a</sup></b>	<b>Recommended Therapy</b>	<b>Epcoritamab Dose Modification</b>							
<b>Grade 1</b> ICE score <sup>c</sup> 7-9 <sup>b</sup> or, depressed level of consciousness <sup>b</sup> : awakens spontaneously	Treatment with dexamethasone <sup>d</sup>  Consider non-sedating anti-seizure medicinal products (e.g., levetiracetam) until resolution of ICANS  No concurrent CRS: • Anti-cytokine therapy not recommended  For ICANS with concurrent CRS: • Treatment with dexamethasone <sup>d</sup> • Choose immunosuppressant alternatives <sup>e</sup> to tocilizumab, if possible	Hold epcoritamab until resolution of event.							

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		<p><b>Grade 2<sup>b</sup></b> ICE score<sup>c</sup> 3-6 or, depressed level of consciousness<sup>b</sup>: awakens to voice</p>	<p>Treatment with dexamethasone<sup>f</sup></p> <p>Consider non-sedating anti-seizure medicinal products (e.g., levetiracetam) until resolution of ICANS</p> <p>No concurrent CRS: • Anti-cytokine therapy not recommended</p> <p>For ICANS with concurrent CRS: • Treatment with dexamethasone<sup>d</sup> • Choose immunosuppressant alternatives<sup>e</sup> to tocilizumab, if possible</p>	<p>Hold epcoritamab until resolution of event.</p>	
		<p><b>Grade 3<sup>b</sup></b> ICE score<sup>c</sup> 0-2 or, depressed level of consciousness<sup>b</sup>: awakens only to tactile stimulus,</p>	<p>Treatment with dexamethasone<sup>g</sup>.</p> <ul style="list-style-type: none"> <li>If no response, initiate methylprednisolone 1 000 mg/day</li> </ul> <p>Consider non-sedating anti-seizure medicinal products (e.g.,</p>	<p>Permanently discontinue epcoritamab.</p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication		Product Registration Holder (PRH)	
		<p>or</p> <p>seizures<sup>b</sup>, either:</p> <ul style="list-style-type: none"> <li>any clinical seizure, focal or generalised that resolves rapidly,</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local oedema<sup>b</sup> on neuroimaging<sup>c</sup></li> </ul>	<p>levetiracetam) until resolution of ICANS</p> <p>No concurrent CRS:</p> <ul style="list-style-type: none"> <li>Anti-cytokine therapy not recommended</li> </ul> <p>For ICANS with concurrent CRS:</p> <ul style="list-style-type: none"> <li>Treatment with dexamethasone                             <ul style="list-style-type: none"> <li>If no response, initiate methylprednisolone 1 000 mg/day</li> </ul> </li> <li>Choose immunosuppressant alternatives<sup>e</sup> to tocilizumab, if possible</li> </ul>		
		<p><b>Grade 4</b></p> <p>ICE score<sup>c, b</sup> 0</p> <p>or, depressed level of consciousness<sup>b</sup></p>	<p>Treatment with dexamethasone<sup>g</sup></p> <ul style="list-style-type: none"> <li>If no response, initiate methylprednisolone 1 000 mg/day</li> </ul> <p>Consider non-sedating anti-seizure</p>	<p>Permanently discontinue epcoritamab .</p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication		Product Registration Holder (PRH)
		<p><i>either:</i></p> <ul style="list-style-type: none"> <li>• <i>patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or</i></li> <li>• <i>stupor or coma, or</i></li> </ul> <p><i>seizures<sup>b</sup>, either:</i></p> <ul style="list-style-type: none"> <li>• <i>life-threatening prolonged seizure (&gt; 5 minutes), or</i></li> <li>• <i>repetitive clinical or electrical seizures</i></li> </ul>	<p><i>medicinal products (e.g., levetiracetam) until resolution of ICANS</i></p> <p><i>No concurrent CRS:</i></p> <ul style="list-style-type: none"> <li>• <i>Anti-cytokine therapy not recommended</i></li> </ul> <p><i>For ICANS with concurrent CRS:</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment with dexamethasone</i> <ul style="list-style-type: none"> <li>o <i>If no response, initiate methylprednisolone 1 000 mg/day</i></li> </ul> </li> <li>• <i>Choose immunosuppressant alternatives e to tocilizumab, if possible</i></li> </ul>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		<p><i>without return to baseline in between, or motor findings<sup>b</sup>:</i></p> <ul style="list-style-type: none"> <li>● <i>deep focal motor weakness such as hemiparesis or paraparesis, or raised intracranial pressure / cerebral oedema<sup>b</sup>, with signs/symptoms such as:</i></li> <li>● <i>diffuse cerebral oedema on neuroimaging,</i></li> </ul>			

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication		Product Registration Holder (PRH)	
		<p><i>or</i></p> <ul style="list-style-type: none"> <li>• <i>decerebrate or decorticate posturing, or</i></li> <li>• <i>cranial nerve VI palsy, or</i></li> <li>• <i>papilloedema, or</i></li> <li>• <i>Cushing’s triad</i></li> </ul>			
		<p><sup>a</sup><i>ICANS graded according to ASTCT ICANS Consensus Grading</i></p> <p><sup>b</sup><i>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</i></p> <p><sup>c</sup><i>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.</i></p>			

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)															
		<p><sup>d</sup>Dexamethasone should be administered at 10 mg intravenously every 12 hours</p> <p><sup>e</sup>Riegler L et al. (2019)</p> <p><sup>f</sup>Dexamethasone 10-20 mg intravenously every 12 hours</p> <p><sup>g</sup>Dexamethasone 10-20 mg intravenously every 6 hours</p>																
		<p><b>Table 6 Recommended dose modifications for other adverse reactions</b></p> <table border="1"> <thead> <tr> <th data-bbox="524 619 936 667">Adverse Reaction<sup>1</sup></th> <th data-bbox="936 619 1285 667">Severity<sup>1</sup></th> <th data-bbox="1285 619 1697 667">Action</th> </tr> </thead> <tbody> <tr> <td data-bbox="524 667 936 975">Infections (see Warnings and Precautions section)</td> <td data-bbox="936 667 1285 975">Grades 1-4</td> <td data-bbox="1285 667 1697 975"> <ul style="list-style-type: none"> <li>Withhold epcoritamab in patients with active infection, until the infection resolves</li> <li>For Grade 4, consider permanent discontinuation of epcoritamab</li> </ul> </td> </tr> <tr> <td data-bbox="524 975 936 1129">Neutropenia or febrile neutropenia (see Undesirable effects section)</td> <td data-bbox="936 975 1285 1129">Absolute neutrophil count less than <math>0.5 \times 10^9</math> /L</td> <td data-bbox="1285 975 1697 1129">Withhold epcoritamab until absolute neutrophil count is <math>0.5 \times 10^9</math> /L or higher</td> </tr> <tr> <td data-bbox="524 1129 936 1284">Thrombocytopenia (see Undesirable effects section)</td> <td data-bbox="936 1129 1285 1284">Platelet count less than <math>50 \times 10^9</math> /L</td> <td data-bbox="1285 1129 1697 1284">Withhold epcoritamab until platelet count is <math>50 \times 10^9</math> /L or higher</td> </tr> <tr> <td data-bbox="524 1284 936 1437">Other adverse reactions (see Undesirable effects section)</td> <td data-bbox="936 1284 1285 1437">Grade 3 or higher</td> <td data-bbox="1285 1284 1697 1437">Withhold epcoritamab until the toxicity resolves to Grade 1 or baseline</td> </tr> </tbody> </table>	Adverse Reaction <sup>1</sup>	Severity <sup>1</sup>	Action	Infections (see Warnings and Precautions section)	Grades 1-4	<ul style="list-style-type: none"> <li>Withhold epcoritamab in patients with active infection, until the infection resolves</li> <li>For Grade 4, consider permanent discontinuation of epcoritamab</li> </ul>	Neutropenia or febrile neutropenia (see Undesirable effects section)	Absolute neutrophil count less than $0.5 \times 10^9$ /L	Withhold epcoritamab until absolute neutrophil count is $0.5 \times 10^9$ /L or higher	Thrombocytopenia (see Undesirable effects section)	Platelet count less than $50 \times 10^9$ /L	Withhold epcoritamab until platelet count is $50 \times 10^9$ /L or higher	Other adverse reactions (see Undesirable effects section)	Grade 3 or higher	Withhold epcoritamab until the toxicity resolves to Grade 1 or baseline	
Adverse Reaction <sup>1</sup>	Severity <sup>1</sup>	Action																
Infections (see Warnings and Precautions section)	Grades 1-4	<ul style="list-style-type: none"> <li>Withhold epcoritamab in patients with active infection, until the infection resolves</li> <li>For Grade 4, consider permanent discontinuation of epcoritamab</li> </ul>																
Neutropenia or febrile neutropenia (see Undesirable effects section)	Absolute neutrophil count less than $0.5 \times 10^9$ /L	Withhold epcoritamab until absolute neutrophil count is $0.5 \times 10^9$ /L or higher																
Thrombocytopenia (see Undesirable effects section)	Platelet count less than $50 \times 10^9$ /L	Withhold epcoritamab until platelet count is $50 \times 10^9$ /L or higher																
Other adverse reactions (see Undesirable effects section)	Grade 3 or higher	Withhold epcoritamab until the toxicity resolves to Grade 1 or baseline																

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<div data-bbox="526 316 1702 416" style="border: 1px solid black; padding: 5px;"> <p><sup>1</sup><i>Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), Version 5.0</i></p> </div> <p><u>Missed or delayed dose</u>                      Diffuse large B-cell lymphoma                      A re-priming Cycle (identical to Cycle 1 with standard CRS prophylaxis) is required:</p> <ul style="list-style-type: none"> <li>● If there are more than 8 days between the priming dose (0.16 mg) and intermediate dose (0.8 mg), or</li> <li>● If there are more than 14 days between the intermediate dose (0.8 mg) and first full dose (48 mg), or</li> <li>● If there are more than 6 weeks between full doses (48 mg)</li> </ul> <p>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).</p> <p><b>Follicular lymphoma</b>                      A re-priming Cycle (identical to Cycle 1 with standard CRS prophylaxis) is required:</p> <ul style="list-style-type: none"> <li>● <b>If there are more than 8 days between the priming dose (0.16 mg) and intermediate dose (0.8 mg), or</b></li> <li>● <b>If there are more than 8 days between the intermediate dose (0.8 mg) and the second intermediate dose (3 mg), or</b></li> <li>● <b>If there are more than 14 days between the second intermediate dose (3 mg) and first full dose (48 mg), or</b></li> </ul>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

Products approved for additional indication (DCA 420 – 7 May 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<ul style="list-style-type: none"> <li>• If there are more than 6 weeks between any two full doses (48 mg)</li> </ul> <p>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).</p> <p><u>Special Populations</u></p> <p>Renal impairment</p> <p>Dose adjustments are not considered necessary in patients with mild to moderate renal impairment. Epcoritamab has not been studied in patients with severe renal impairment to end stage renal disease. No dose recommendations can be made for patients with severe renal impairment to end-stage renal disease (see Pharmacokinetic properties section).</p> <p>Hepatic impairment</p> <p>Dose adjustments are not considered necessary in patients with mild hepatic impairment. Epcoritamab has not been studied in patients with severe hepatic impairment (defined as total bilirubin &gt; 3 times ULN and any AST) and data are limited in patients with moderate hepatic impairment (defined as total bilirubin &gt; 1.5 to 3 times ULN and any AST). No dose recommendations can be made for patients with moderate to severe hepatic impairment (see Pharmacokinetic properties section).</p> <p>Elderly</p> <p>No dose adjustment is necessary in patients ≥ 65 years of age (see Pharmacodynamic properties and Pharmacokinetic properties sections).</p>	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 420, 7 Mei 2026

*Products approved for additional indication (DCA 420 – 7 May 2026)*

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<p>Paediatric population</p> <p>The safety and efficacy of Epkinly in children aged less than 18 years of age have not yet been established. No data are available.</p> <p><u>Method of administration</u></p> <p>Epkinly is for subcutaneous use. It should be administered by subcutaneous injection only, preferably in the lower part of the abdomen or the thigh. Change of injection site from left to right side or vice versa is recommended especially during the weekly administration schedule (i.e., Cycles 1-3).</p> <p>For instructions on reconstitution of the medicinal product before administration, see Special precautions for disposal and other handling section.</p>	