Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 387, 3 Ogos 2023

Products approved for additional indication (DCA 387 – 3 August 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	MONUROL 3G GRANULES [Fosfomycin Trometamol 5.631gm, equivalent to 3.0gm fosfomycin]	**INDICATION :** Monurol is indicated for perioperative antibiotic prophylaxis for transrectal prostate biopsy in adult man. Consideration should be given to official guidance on the appropriate use of antibacterial agents, especially to avoid increasing antibiotic resistance. **POSOLOGY :** Perioperative antibiotic prophylaxis for transrectal prostate biopsy: 1 sachet of Monurol 3g approx. 3 hours before, and 24 hours after the procedure. <u>Method of Administration</u> For oral use. For the indication of acute uncomplicated lower urinary tract infections (acute cystitis), Monural should be taken on an empty stomach (about 2-3 hours before or 2-3 hours after a meal), preferably before bedtime and after emptying the bladder. The dose should be dissolved into a glass of water (50 – 75 ml) and taken immediately after its preparation.	**EP PLUS GROUP SDN. BHD.** Block C-3-1, Plaza Mont Kiara, No. 2, Jalan Kiara, Mont Kiara, 50480 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	FORXIGA 5MG FILM-COATED TABLET [Dapagliflozin propanediol 6.15mg, equivalent to dapagliflozin 5mg] FORXIGA 10MG FILM-COATED TABLET [Dapagliflozin propanediol 12.30mg, equivalent to dapagliflozin 10mg]	**INDICATION :** <u>Heart failure</u> Forxiga is indicated in adults for the treatment of symptomatic chronic heart failure. **POSOLOGY :** <u>Heart failure</u> The recommended dose is 10mg dapagliflozin once daily. In the DAPA-HF and DELIVER studies, dapagliflozin was administered in conjunction with other heart failure therapies.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

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<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>3.</td><td>Evrysdi Powder for oral solution 0.75 mg/mL

[Risdiplam 0.75mg/mL]</td><td>
INDICATION :

EVRYSDI is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

POSOLOGY :

Dosing Information

EVRYSDI is administered orally once daily. The recommended dosage is determined by age and body weight (see Table 1).

Table 1 Adult and Pediatric Dosing Regimen by Age and Body Weight
<table>
<tr><th>Age and Body Weight</th><th>Recommended Daily Dosage</th></tr>
<tr><td>Less than 2 months of age</td><td>0.15mg/kg</td></tr>
<tr><td>2 months to less than 2 years of age</td><td>0.2 mg/kg</td></tr>
<tr><td>2 years of age and older weighing less than 20 kg</td><td>0.25 mg/kg</td></tr>
<tr><td>2 years of age and older weighing 20 kg or more</td><td>5 mg</td></tr>
</table>
</td><td>ROCHE (MALAYSIA) SDN. BHD.
Level 21, The Pinnacle,
Persiaran Lagoon,
Bandar Sunway,
47500 Subang Jaya,
Selangor.</td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	POLIVY 140mg Powder For Concentrate For Solution For Infusion [Polatuzumab Vedotin]	**INDICATION :** Polivy in combination with rituximab, cyclophosphamide, doxorubicin, and prednisolone (or prednisone) (R-CHP) is indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL). **POSOLOGY :** Polivy must only be administered under the supervision of a healthcare professional experienced in the diagnosis and treatment of cancer patients. <u>Posology</u> Diffuse large B-cell lymphoma Previously untreated patients The recommended dose of Polivy is 1.8 mg/kg, given as an intravenous infusion every 21 days in combination with rituximab, cyclophosphamide, doxorubicin, and prednisolone (or prednisone) (R-CHP) for 6 cycles. Polivy, rituximab, cyclophosphamide and doxorubicin can be administered in any order on Day 1 after the administration of prednisolone (or prednisone). Prednisolone (or prednisone) is administered on Days 1-5 of each cycle. Cycles 7 and 8 consist of rituximab as monotherapy. Refer to the summary of package insert of chemotherapy agents given in combination with Polivy for patients with previously untreated DLBCL. Relapsed or refractory patients The recommended dose of Polivy is 1.8 mg/kg, given as an intravenous infusion every 21 days in combination with bendamustine and rituximab for 6 cycles. Polivy,	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		bendamustine and rituximab can be administered in any order on Day 1 of each cycle. When administered with Polivy, the recommended dose of bendamustine is 90 mg/m^2/day on Day 1 and Day 2 of each cycle and the recommended dose of rituximab is 375 mg/m^2 on Day 1 of each cycle. Due to limited clinical experience in patients treated with 1.8 mg/kg Polivy at a total dose >240 mg, it is recommended not to exceed the dose 240 mg/cycle. Previously untreated and relapsed or refractory patients If not already premedicated, premedication with an antihistamine and anti-pyretic should be administered to patients prior to Polivy. Delayed or missed doses If a planned dose of Polivy is missed, it should be administered as soon as possible and the schedule of administration should be adjusted to maintain a 21-day interval between doses. Dose modifications The infusion rate of Polivy should be slowed or interrupted if the patient develops an infusion-related reaction. Polivy should be discontinued immediately and permanently if the patient experiences a life-threatening reaction. There are different potential dose modifications for Polivy in patients with previously untreated DLBCL and those who are relapsed or refractory. For dose modifications to manage peripheral neuropathy (section 4.4) see Table 1 below. Table 1 Polivy dose modifications for peripheral neuropathy (PN)	

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<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Indication</th><th>Severity of PN on Day 1 of any cycle</th><th>Dose modification</th></tr>
<tr><td>Previously untreated DLBCL</td><td>Grade 2 [a]</td><td>Sensory neuropathy:
Reduce Polivy to 1.4 mg/kg.
If Grade 2 persists or recurs at Day 1 of a future cycle, reduce Polivy to 1.0 mg/kg.
If already at 1.0 mg/kg and Grade 2 occurs at Day 1 of a future cycle, discontinue Polivy.
Motor neuropathy:
Withhold Polivy dosing until improvement to Grade ≤ 1.
Restart Polivy at the next cycle at 1.4 mg/kg
If already at 1.4 mg/kg and Grade 2 occurs at Day 1 of a future cycle, withhold Polivy dosing until improvement to Grade ≤ 1. Restart Polivy at 1.0 mg/kg.
If already at 1.0 mg/kg and Grade 2 occurs at Day 14 1 of a future cycle, discontinue Polivy.
If concurrent sensory and motor neuropathy, follow the most severe restriction recommendation above.</td></tr>
</table>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
			Grade 3[a]	Sensory neuropathy: • Withhold Polivy dosing until improvement to Grade ≤ 2. • Reduce Polivy to 1.4 mg/kg. • If already at 1.4 mg/kg, reduce Polivy to 1.0 mg/kg. If already at 1.0 mg/kg, discontinue Polivy. Motor neuropathy: • Withhold Polivy dosing until improvement to Grade ≤ 1. • Restart Polivy at the next cycle at 1.4 mg/kg. • If already at 1.4 mg/kg and Grade 2–3 occurs, withhold Polivy dosing until improvement to Grade ≤ 1. Restart Polivy at 1.0 mg/kg. • If already at 1.0 mg/kg and Grade 2–3 occurs, discontinue Polivy. If concurrent sensory and motor neuropathy, follow the most severe restriction recommendation above.	
			Grade 4	Discontinue Polivy	

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<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>R/R DLBCL</td><td>Grade 2–3</td><td>Withhold Polivy dosing until improvement to ≤ Grade 1. If recovered to Grade ≤ 1 on or before Day 14, restart Polivy at a permanently reduced dose of 1.4 mg/kg. If a prior dose reduction to 1.4 mg/kg has occurred, discontinue Polivy.

If not recovered to Grade ≤ 1 on or before Day 14, discontinue Polivy.</td></tr>
<tr><td></td><td>Grade 4</td><td>Discontinue Polivy.</td></tr>
</table>
[a] R-CHP may continue to be administered.

For dose modifications to manage myelosuppression (section 4.4) see Table 2 below.

Table 2 Polivy, chemotherapy and rituximab dose modifications to manage myelosuppression

<table>
<tr><td>Indication</td><td>Severity of myelosuppression on Day 1 of any cycle</td><td>Dose modification</td></tr>
<tr><td>Previously untreated DLBCL</td><td>Grade 3–4 Neutropenia</td><td>Withhold all treatment until ANC* recovers to > 1000/µL.
If ANC recovers to > 1000/µL on or before Day 7, resume all treatment without any dose reductions.

If ANC recovers to > 1000/µL after Day 7:
• resume all treatment; consider a dose reduction of cyclophosphamide and/or doxorubicin by 25-50%.</td></tr>
</table>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
				• if cyclophosphamide and/or doxorubicin are already reduced by 25%, consider reducing one or both agents to 50%.	
			Grade 3–4 Thrombocytopenia	Withhold all treatment until platelets recover to > 75,000/µL. If platelets recover to > 75,000/µL on or before Day 7, resume all treatment without any dose reductions. If platelets recover to > 75,000/µL after Day 7: • resume all treatment; consider a dose reduction of cyclophosphamide and/or doxorubicin by 25-50%. • if cyclophosphamide and/or doxorubicin are already reduced by 25%, consider reducing one or both agents to 50%.	
		R/R DLBCL	Grade 3-4 Neutropenia [1]	Withhold all treatment until ANC recovers to > 1000/µL. If ANC recovers to > 1000/µL on or before Day 7, resume all treatment without any additional dose reductions. If ANC recovers to > 1000/µL after Day 7: • restart all treatment with a dose reduction of bendamustine from 90 mg/m^2 to 70 mg/m^2 or 70 mg/m^2 to 50 mg/m^2. • if a bendamustine dose reduction to 50 mg/m^2 has already occurred, discontinue all treatment.	

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<tr><th>No.</th><th>Product
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<tr><td></td><td></td><td>
<table>
<tr><td></td><td>Grade 3-4 Thrombocytopenia [1]</td><td>Withhold all treatment until platelets recover to >75,000/µL.
If platelets recover to > 75,000/µL on or before Day 7, resume all treatment without any dose reductions.
If platelets recover to > 75,000/µL after Day 7:
restart all treatment with a dose reduction of bendamustine from 90 mg/m^2 to 70 mg/m^2 or 70 mg/m^2 to 50 mg/m^2.
if a bendamustine dose reduction to 50 mg/m^2 has already occurred, discontinue all treatment.</td></tr>
</table>
[1]If primary cause is due to lymphoma, the dose of bendamustine may not need to be reduced.
*ANC: absolute neutrophil count

For dose modifications to manage infusion-related reactions (section 4.4) see Table 3 below.

Table 3 Polivy dose modifications for infusion-related reactions (IRRs)
<table>
<tr><th>Indication</th><th>Severity of IRR on Day 1 of any cycle</th><th>Dose modification</th></tr>
</table>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		Previously untreated and R/R DLBCL	Grade 1–3 IRR	Interrupt Polivy infusion and give supportive treatment. For the first instance of Grade 3 wheezing, bronchospasm, or generalized urticaria, permanently discontinue Polivy. For recurrent Grade 2 wheezing or urticaria, or for recurrence of any Grade 3 symptoms, permanently discontinue Polivy. Otherwise, upon complete resolution of symptoms, infusion may be resumed at 50% of the rate achieved prior to interruption. In the absence of infusion-related symptoms, the rate of infusion may be escalated in increments of 50 mg/hour every 30 minutes. For the next cycle, infuse Polivy over 90 minutes. If no infusion-related reaction occurs, subsequent infusions may be administered over 30 minutes. Administer premedication for all cycles.	
			Grade 4 IRR	Stop Polivy infusion immediately. Give supportive treatment. Permanently discontinue Polivy.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	NOVOSEVEN 1MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION [1 mg/vial (50 KIU) Eptacog alfa (activated) (Recombinant coagulation factor VIIa)] NOVOSEVEN 2MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION [2 mg/vial (100 KIU) Eptacog alfa (activated) (Recombinant coagulation factor VIIa)]	**INDICATION :** <u>Severe postpartum haemorrhage</u> NovoSeven is indicated for the treatment of severe postpartum haemorrhage when uterotonics are insufficient to achieve haemostasis. **POSOLOGY :** <u>Severe postpartum haemorrhage</u> Dose range and dose interval The recommended dose range for the treatment of bleeding is 60 – 90 µg per kg body weight administered by intravenous bolus injection. Peak coagulant activity can be expected at 10 minutes. A second dose can be administered based on clinical response of the individual patient. It is recommended that in case of insufficient haemostatic response, a second dose can be administered after 30 minutes	**NOVO NORDISK PHARMA (MALAYSIA) SDN. BHD.** Menara 1 Sentrum, Level 16, No. 201, Jalan Tun Sambathan, 50470 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.