

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 425, 8 Oktober 2026

Products approved for additional indication (DCA 425 – 8 October 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Olumiant 2mg Film-Coated Tablets [Baricitinib 2mg] Olumiant 4mg Film-Coated Tablets [Baricitinib 4mg]	INDICATION: <u>Alopecia areata</u> Baricitinib is indicated for the treatment of severe alopecia areata in adult and adolescent patients 12 years of age and older. POSODOLOGY: Alopecia areata <u>Adolescents (12 years of age and older)</u> The recommended dose of baricitinib is 4 mg once daily for patients weighing 30 kg or more. See Paediatric population below for information on patients weighing less than 30 kg. A dose of 2 mg once daily should be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering. Once a stable response has been achieved, it is recommended to continue treatment for at least several months, in order to avoid relapse. The benefit risk of treatment should be reassessed at regular intervals on an individual basis. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 36 weeks of treatment. <u>Paediatric population</u> The safety and efficacy of baricitinib in children less than 2 years with atopic dermatitis and	ZUELLIG PHARMA SDN. BHD. No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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		juvenile idiopathic arthritis have not yet been established. No data are available. The safety and efficacy of baricitinib in children less than 12 years of age or weighing < 30 kg with alopecia areata have not yet been established. No data are available.	
2.	Koselugo Hard Capsules 10 mg [Selumetinib 12.1mg (corresponds to 10mg of selumetinib free base)] Koselugo Hard Capsules 25 mg [Selumetinib 30.25mg (corresponds to 25mg of selumetinib free base)]	INDICATION: Koselugo as monotherapy is indicated for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in adult and paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and older. POSODOLOGY: <u>Posology</u> The recommended dose of Koselugo is 25 mg/m² of body surface area (BSA), taken orally twice daily (approximately every 12 hours). Dosing in adult and paediatric patients is individualised based on BSA (mg/m²) and rounded to the nearest achievable 5 mg or 10 mg dose (up to a maximum single dose of 50 mg). Different strengths of Koselugo capsules can be combined to attain the desired dose (Table 1).	ASTRAZENECA SDN. BHD. Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiarra Damansara, 47800 Petaling Jaya, Selangor.

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		Table 1. Recommended dose based on body surface area <table><tr><th>Body surface area (BSA)^a</th><th>Recommended dose</th></tr><tr><td>0.55 – 0.69 m²</td><td>20 mg in the morning and 10 mg in the evening</td></tr><tr><td>0.70 – 0.89 m²</td><td>20 mg twice daily</td></tr><tr><td>0.90 – 1.09 m²</td><td>25 mg twice daily</td></tr><tr><td>1.10 – 1.29 m²</td><td>30 mg twice daily</td></tr><tr><td>1.30 – 1.49 m²</td><td>35 mg twice daily</td></tr><tr><td>1.50 – 1.69 m²</td><td>40 mg twice daily</td></tr><tr><td>1.70 – 1.89 m²</td><td>45 mg twice daily</td></tr><tr><td>≥ 1.90 m²</td><td>50 mg twice daily</td></tr></table> ^aThe recommended dose for patients with a BSA less than 0.55 m² has not been established. Treatment with Koselugo should continue as long as clinical benefit is observed, or until PN progression or the development of unacceptable toxicity. <u>Ethnicity</u> Increased systemic exposure has been seen in adult Asian subjects, although there is considerable overlap with Western subjects when corrected for body weight. No specific adjustment to the starting dose is recommended for Asian patients, however these patients, should be closely monitored for adverse events.	Body surface area (BSA) ^a	Recommended dose	0.55 – 0.69 m ²	20 mg in the morning and 10 mg in the evening	0.70 – 0.89 m ²	20 mg twice daily	0.90 – 1.09 m ²	25 mg twice daily	1.10 – 1.29 m ²	30 mg twice daily	1.30 – 1.49 m ²	35 mg twice daily	1.50 – 1.69 m ²	40 mg twice daily	1.70 – 1.89 m ²	45 mg twice daily	≥ 1.90 m ²	50 mg twice daily	
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		<u>Elderly population</u> The safety and efficacy of Koselugo in adults with NF1-PN older than 65 years of age has not been established. No data are currently available in NF1-PN patients 65 years of age and older.	
3.	WINREVAIR® 45mg Powder and Solvent for Solution for Injection WINREVAIR® 60mg Powder and Solvent for Solution for Injection [Sotatercept 50 mg/mL]	INDICATION: Winrevair, in combination with other pulmonary arterial hypertension (PAH) therapies, is indicated for the treatment of PAH in adult patients with WHO Functional Class (FC) II, III, and IV. POSOLOGY: <u>Posology</u> Winrevair is administered once every 3 weeks as a single subcutaneous injection according to patient weight. <u>Recommended starting dose</u> Haemoglobin (Hgb) and platelet count should be obtained prior to the first dose. Initiation of treatment is contraindicated if platelet count is consistently $< 50 \times 10^9 /L$. Treatment is initiated with a single dose of 0.3 mg/kg (see Table 1).	MERCK SHARP & DOHME (MALAYSIA) SDN. BHD. Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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		Table 1: Injection volume for dose of 0.3 mg/kg <table><thead><tr><th>Patient weight range (kg)</th><th>Injection volume (mL)*</th><th>Dose vial</th></tr></thead><tbody><tr><td>30.0 – 40.8</td><td>0.2</td><td rowspan="8">Kit containing 1 x 45mg vial</td></tr><tr><td>40.9 – 57.4</td><td>0.3</td></tr><tr><td>57.5 – 74.1</td><td>0.4</td></tr><tr><td>74.2 – 90.8</td><td>0.5</td></tr><tr><td>90.9 – 107.4</td><td>0.6</td></tr><tr><td>107.5 – 124.1</td><td>0.7</td></tr><tr><td>124.2 – 140.8</td><td>0.8</td></tr><tr><td>140.9 – 157.4</td><td>0.9</td></tr><tr><td>157.5 – 174.1</td><td>1.0</td><td rowspan="2">Kit containing 1 x 60mg vial</td></tr><tr><td>174.2 – 180.0</td><td>1.1</td></tr></tbody></table> *The concentration of the reconstituted solution is 50 mg/mL <u>Recommended target dose</u> Three weeks after a single starting dose of 0.3 mg/kg, the dose should be escalated to the recommended target dose of 0.7 mg/kg after verifying acceptable Hgb and platelet count (see section “Dose adjustments due to increase in haemoglobin or decreased platelet count”). Treatment should be continued at 0.7 mg/kg every 3 weeks unless dose adjustments are required.	Patient weight range (kg)	Injection volume (mL)*	Dose vial	30.0 – 40.8	0.2	Kit containing 1 x 45mg vial	40.9 – 57.4	0.3	57.5 – 74.1	0.4	74.2 – 90.8	0.5	90.9 – 107.4	0.6	107.5 – 124.1	0.7	124.2 – 140.8	0.8	140.9 – 157.4	0.9	157.5 – 174.1	1.0	Kit containing 1 x 60mg vial	174.2 – 180.0	1.1	
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		Table 2: Injection volume for dose of 0.7 mg/kg			
		Patient weight range (kg)	Injection volume (mL)*	Dose vial	
		30.0 – 31.7	0.4	Kit containing 1 x 45mg vial	
		31.8 – 38.9	0.5		
		39.0 – 46.0	0.6		
		46.1 – 53.2	0.7		
		53.3 – 60.3	0.8		
		60.4 – 67.4	0.9		
		67.5 – 74.6	1.0	Kit containing 1 x 60mg vial	
		74.7 – 81.7	1.1		
		81.8 – 88.9	1.2		
		89.0 – 96.0	1.3	Kit containing 2 x 45mg vial	
		96.1 – 103.2	1.4		
		103.3 – 110.3	1.5		
		110.4 – 117.4	1.6		
		117.5 – 124.6	1.7		
		124.7 – 131.7	1.8		
		131.8 – 138.9	1.9	Kit containing 2 x 60mg	

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		139.0 – 146.0	2.0	vial	
		146.1 – 153.2	2.1		
		153.3 – 160.3	2.2		
		160.4 – 167.4	2.3		
		167.5 and above	2.4		
		*The concentration of the reconstituted solution is 50 mg/mL			
<u>Dose adjustments due to increase in haemoglobin or decreased platelet count</u>					
Hgb and platelet count should be monitored for the first 5 doses, or longer if values are unstable. Thereafter, Hgb and platelet count should be verified every 3 to 6 months and the dose adjusted if necessary.					
Treatment should be delayed for 3 weeks (i.e., one dose delay) if any of the following occur:					
• Hgb increases > 1.24 mmol/L (2 g/dL) from the previous dose and is above the upper limit of normal (ULN). • Hgb increases > 2.48 mmol/L (4 g/dL) from baseline. • Hgb increases > 1.24 mmol/L (2 g/dL) above ULN. • Platelet count decreases < 50 x 10⁹ /L.					
Hgb and platelet count should be obtained again before reinitiating treatment.					

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		For treatment delays lasting > 9 weeks, treatment should be restarted at 0.3 mg/kg, and the dose should be escalated to 0.7 mg/kg after verifying acceptable Hgb and platelet count. For treatment delays lasting > 9 weeks due to platelet counts consistently < 50 x 10⁹ /L, the physician should carry out a benefit/risk re-evaluation for the patient before reinitiating treatment. <u>Missed dose</u> If a dose is missed, administer as soon as possible. If the missed dose is not taken within 3 days of the scheduled date, adjust the schedule to maintain 3-week dosing intervals. <u>Elderly</u> No dose adjustment is required in elderly patients ≥ 65 years old. <u>Renal impairment</u> No dose adjustment is required based on renal impairment. Limited data are available on the use of sotatercept in PAH patients with severe renal impairment (estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m²).	

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		<u>Hepatic impairment</u> No dose adjustment is required based on hepatic impairment (Child-Pugh Classification A to C). Sotatercept has not been studied in patients with hepatic impairment. <u>Paediatric population</u> The safety and efficacy of Winrevair in children and adolescents below 18 years of age have not yet been established. No data are available.	
4.	Enhertu Powder For Concentrate For Solution For Infusion 100 mg/vial [Trastuzumab Deruxtecan 100mg/5ml]	INDICATION: Enhertu as monotherapy is indicated for the treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen. POSODOLOGY: <u>Patient Selection</u> Gastric cancer Patients treated with trastuzumab deruxtecan for gastric or gastroesophageal junction cancer should have documented HER2-positive tumour status, defined as a score of 3 + by immunohistochemistry (IHC) or a ratio of ≥ 2 by in situ hybridization (ISH) or by fluorescence in situ hybridization (FISH), assessed by a CE-marked in vitro diagnostic (IVD) medical device. If a CE-marked IVD is not available, the HER2 status should be assessed by an alternate validated test.	ASTRAZENECA SDN. BHD. Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

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		<u>Posology</u> Gastric cancer The recommended dose of Enhertu is 6.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. The initial dose should be administered as a 90-minute intravenous infusion. If the prior infusion was well tolerated, subsequent doses of Enhertu may be administered as 30-minute infusions. The infusion rate of Enhertu should be slowed or interrupted if the patient develops infusion-related symptoms (see section 4.8). Enhertu should be permanently discontinued in case of severe infusion reactions.	