Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 383, 6 April 2023

Products approved for additional indication (DCA 383 – 6 April 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Entresto 50mg Film-coated Tablets Entresto 100mg Film-coated Tablets Entresto 200mg Film-coated Tablets [Sacubitril/Valsartan (corresponds to 50mg LCZ696 free anhydrous acid (sacubitril 24.3mg and valsartan 25.7mg) Sacubitril/Valsartan (corresponds to 100mg LCZ696 free anhydrous acid (sacubitril 48.6mg and valsartan 51.4mg) Sacubitril/Valsartan (corresponds to 200mg LCZ696 free anhydrous acid (sacubitril 97.2mg and valsartan 102.8mg)]	**INDICATION :** Hypertension Entresto is indicated for the treatment of essential hypertension. Entresto should not be used as a first-line drug for the treatment of hypertension because of the risk of excessive decrease in blood pressure. **POSOLOGY :** **Hypertension** The recommended starting dose of Entresto is 200 mg once daily. In patients whose blood pressure could not be adequately controlled with Entresto 200 mg once daily, the dose can be increased to 400mg once daily. In hypertensive patients with heart failure, the heart failure dosing is recommended. Entresto may be used alone or in combination with other antihypertensive agents except angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs). <u>Special populations</u> Elderly population The dose should be in line with the renal function of the elderly patient. Renal impairment No dose adjustment is required in patients with mild (Estimated Glomerular Filtration Rate [eGFR] 60-90 ml/min/1.73 m^2) renal impairment. A starting dose of 50 mg twice daily should be considered in heart failure patients with moderate renal impairment (eGFR 30-60 ml/min/1.73 m^2). As there is very limited clinical	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 383, 6 April 2023

Products approved for additional indication (DCA 383 – 6 April 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		experience in heart failure patients with severe renal impairment (eGFR <30 ml/min/1.73 m^2). Entresto should be used with caution and a starting dose of 50 mg twice daily is recommended. Safety and efficacy of Entresto in patients with essential hypertension and with severe renal impairment (eGFR <30 ml/min/1.73 m^2) have not been established. Hepatic impairment No dose adjustment is required when administering Entresto to patients with mild hepatic impairment (Child-Pugh A classification). There is limited clinical experience in patients with moderate hepatic impairment (Child-Pugh B classification) or with AST/ALT values more than twice the upper limit of the normal range. Entresto should be used with caution in these heart failure patients and the recommended starting dose is 50 mg twice daily. A starting dose of 100 mg once daily is recommended for essential hypertensive patients with moderate hepatic impairment (Child-Pugh B classification). Entresto is contraindicated in patients with severe hepatic impairment, biliary cirrhosis or cholestasis (Child-Pugh C classification). Paediatric population The safety and efficacy of Entresto in children and adolescents aged below 18 years have not been established. No data are available. <u>Method of administration</u> Oral use. Entresto may be administered with or without food. The tablets must be swallowed with a glass of water.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 383, 6 April 2023

Products approved for additional indication (DCA 383 – 6 April 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	RINVOQ 15mg Extended Release Film Coated Tablets [Upadacitinib Hemihydrate (Corresponds to 15 mg of upadacitinib)]	**INDICATION :** Ankylosing spondylitis (AS, radiographic axial spondyloarthritis) RINVOQ is indicated for the treatment of active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy. **POSOLOGY :** Rheumatoid arthritis, psoriatic arthritis and **ankylosing spondylitis** The recommended dose of upadacitinib is 15 mg once daily. Consideration should be given to discontinuing treatment in patients with ankylosing spondylitis who have shown no clinical response after 16 weeks of treatment. Some patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks.	**ABBVIE SDN. BHD.** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 383, 6 April 2023

Products approved for additional indication (DCA 383 – 6 April 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	EVUSHELD 100 MG/ML SOLUTION FOR INJECTION [Tixagevimab 100 mg/mL and Cilgavimab 100 mg/mL]	**INDICATION :** Treatment EVUSHELD is indicated for the treatment of adults and adolescents (aged 12 years and older weighing at least 40kg) with COVID-19, who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. **POSOLOGY :** The recommended dosage is 600 mg of EVUSHELD, administered as two separate, sequential, injections of: • 300 mg of tixagevimab • 300 mg of cilgavimab Pre-exposure prophylaxis <u>Dosing for Individuals Who Initially Received 300mg EVUSHELD (150 mg of Tixagevimab and 150 mg of Cilgavimab):</u> Individuals who have already received the previously approved initial dose of 300mg EVUSHELD (150 mg tixagevimab and 150 mg cilgavimab) should receive an additional EVUSHELD dose as soon as possible, with the dose based on the following criteria: • If the patient received their initial dose ≤ 3 months ago, the patient should receive a dose of 300mg EVUSHELD (150 mg of tixagevimab and 150 mg of cilgavimab). • If the patient received their initial dose > 3 months ago, the patient should receive a dose of 600mg EVUSHELD (300mg of tixagevimab and 300 mg of cilgavimab).	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 383, 6 April 2023

Products approved for additional indication (DCA 383 – 6 April 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		For individuals who require repeat dosing for ongoing prevention of COVID-19, subsequent doses of 600mg of EVUSHELD (300mg of tixagevimab and 300 mg of cilgavimab) should be given once every 6 months. The dose recommendations for prophylaxis are based on the totality of the available data including clinical pharmacology, pharmacokinetics (PK), antiviral activity, and clinical trial data. EVUSHELD has only been studied for the prophylaxis of COVID-19 at the 300 mg dose. The clinical safety of 600 mg EVUSHELD for prophylaxis use is supported by safety data from TACKLE in patients with mild to moderate COVID-19. Treatment EVUSHELD should be given as soon as possible after a positive viral test for SARS-CoV-2 and within 7 days after the onset of symptoms.	