Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 366 – 17 November 2021)

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>1.</td><td>HUMIRA Solution for Injection in Prefilled syringe 80MG/0.8ML [Adalimumab 80mg/0.8mL]

HUMIRA Solution for Injection in Prefilled PEN 80MG/0.8ML [Adalimumab 80mg/0.8mL]

Humira Solution for Injection in Pre-filled Syringe 40mg/0.4ml [Adalimumab 40mg/0.4mL]

Humira Solution for Injection in Pre-filled Pen 40mg/0.4ml [Adalimumab 40mg/0.4mL]</td><td>INDICATION :

<u>Pediatric Ulcerative Colitis</u>
Humira is indicated for treatment of moderately to severely active ulcerative colitis in patients aged 6 years and above who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

POSOLOGY:

Paediatric Ulcerative Colitis
The recommended dose of Humira for patients from 6 to 17 years of age with ulcerative colitis is based on body weight (Table 6). Humira is administered via subcutaneous injection. Humira may be available in different strengths and/or presentations.

Table 6. Humira Dose for Pediatric Ulcerative Colitis
<table><tr><th>Patient Weight</th><th>Induction Dose</th><th>Maintenance Dose Starting at Week 4</th></tr><tr><td>< 40 kg</td><td>• 80 mg at Week 0 and
• 40 mg at Week 2</td><td>• 40 mg every other week or
• 20mg every week</td></tr><tr><td>≥ 40 kg</td><td>• 160 mg at week 0 and
• 80 mg at week 2</td><td>• 80 mg every other week or
• 40mg every week</td></tr></table></td><td>ABBVIE SDN. BHD.
9th Floor Menara Lien Hoe,
No.8, Persiaran Tropicana,
Tropicana Golf & Country Resort,
47410 Petaling Jaya,
Selangor.</td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
	HUMIRA Solution for Injection in Prefilled syringe 20MG/0.2ML [Adalimumab 20mg/0.2mL]	* Pediatric patients who turn 18 years of age while on Humira should continue their prescribed maintenance dose. Continued therapy beyond 8 weeks should be carefully considered in patients not showing signs of response within this time period. There is no relevant use of Humira in children aged less than 6 years in this indication.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** Triple-Negative Breast Cancer KEYTRUDA, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥10) as determined by a validated test. **POSOLOGY** : **Recommended Dosing** KEYTRUDA is administered as an intravenous infusion over 30 minutes. The recommended dose of KEYTRUDA with head and neck cancer, cHL, urothelial carcinoma, RCC, adjuvant treatment of melanoma, endometrial carcinoma, previously untreated NSCLC, colorectal cancer, esophageal cancer, or **triple-negative breast cancer** is either: 200mg every 3 weeks or 400mg every 6 weeks.	**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.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	FORXIGA 5MG FILM-COATED TABLET [Dapagliflozin propanediol 6.150mg, equivalent to dapagliflozin 5mg] FORXIGA 10MG FILM-COATED TABLET [Dapagliflozin propanediol 12.30mg, equivalent to dapagliflozin 10mg]	**INDICATION :** <u>Chronic kidney disease</u> Forxiga is indicated in adults for the treatment of chronic kidney disease. **POSOLOGY :** <u>Chronic kidney disease</u> The recommended dose is 10mg dapagliflozin once daily. In the DAPA-CKD study, dapagliflozin was administered in conjunction with other chronic kidney disease therapies. <u>Special populations</u> Renal impairment No dosage adjustment is required based on renal function. Due to limited experience, it is not recommended to initiate treatment with dapagliflozin in patients with GFR <25 mL/min. In patients with diabetes mellitus, the glucose lowering efficacy of dapagliflozin is reduced when the glomerular filtration rate is <45 ml/min, and is likely absent in patients with severe renal impairment. Therefore, if GRF falls below 45 mL/min, additional glucose lowering treatment should be considered in patients with diabetes mellitus if further glycaemic control is needed.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	NORVASC TABLET 5MG [Amlodipine Besylate 5mg]	**POSOLOGY :** **Use in Children** Children and adolescents with hypertension from 6 years to 17 years of age. The recommended antihypertensive oral dose in pediatric patients aged 6 -17 years is 2.5 mg once daily as a starting dose, up-titrated to 5 mg once daily if blood pressure goal is not achieved after 4 weeks. Doses in excess of 5 mg daily have not been studied in pediatric patients. **Children under 6 years old** No data are available.	**UPJOHN (MALAYSIA) SDN. BHD.** Level 9-2, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Bangsar, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	COVID-19 Vaccine AstraZeneca Solution for Injection [One dose (0.5 ml) contains: COVID-19 Vaccine (ChAdOx1-S * recombinant), not less than 2.5 x 10^8 infectious units (inf U), which corresponds to 5 × 10^{10} viral particles (vp) **Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.]*	**POSOLOGY :** <u>Individuals 18 years of age and older</u> The COVID-19 Vaccine AstraZeneca primary vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 and 12 weeks (28 to 84 days) after the first dose (see section 5.1). There are no data available on the interchangeability of COVID-19 Vaccine AstraZeneca with other COVID-19 vaccines to complete the vaccination course. Individuals who have received the first dose of COVID-19 Vaccine AstraZeneca should receive the second dose of COVID-19 Vaccine AstraZeneca to complete the vaccination course. **A booster dose of 0.5ml COVID-19 Vaccine AstraZeneca may be administered at least 6 months after the second dose of COVID 19 Vaccine AstraZeneca when the potential benefits outweigh any potential risks.** **The decision when and for whom to implement a booster dose of the vaccine should be made based on available vaccine effectiveness data, taking into account limited safety data (see clinical section).**	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
6.	CoronaVac Suspension for Injection SARS-CoV-2 Vaccine (Vero Cell), Inactivated CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated [Each dose (0.5 mL) contains 600 SU (equivalent to 3µg) of inactivated SARS-CoV-2 (CZ02 strain) (Vero cell) antigen]	**POSOLOGY :** Individuals 18 years of age and older Two doses should be administered for primary immunization. The second dose is preferably given 14 - 28 days after the first dose. 0.5 mL per dose. **A booster dose of (0.5ml) may be administered at least 3-6 months after the second dose when the potential benefits outweigh any potential risks.** **The decision when and for whom to implement a booster dose of the vaccine should be made based on available vaccine effectiveness data, taking into account limited safety data (see clinical section).** Children and adolescent 12-17 years of age Two doses should be administered for primary immunization. The second dose is preferably given 28 days after the first dose. 0.5 mL per dose. Elderly population No dosage adjustment is required in elderly individuals ≥ 60 years of age. There is limited data on the use of CoronaVac in individuals ≥ 60 years of age. CoronaVac, when administered to individuals ≥ 60 years of age, has shown adequate and similar neutralizing antibodies titres as in adults. At present, it is recommended that vaccination for people aged 60 and above should be considered cautiously and its necessity should be evaluated based on their health condition and exposure risk.	**PHARMANIAGA LIFESCIENCE SDN. BHD.** Lot 7, Jalan PPU 3, Taman Perindustrian Puchong Utama, 47100 Puchong, Selangor.