Maklumat tambahan indikasi

Tahun 2022

Products Approved For Additional Indication (DCA 368 – 6 Januari 2022)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Keytruda 100mg Solution for Infusion [Pembrolizumab 100mg]	**INDICATION :** Esophageal Cancer KEYTRUDA, in combination with platinum and fluoropyrimidine based chemotherapy, is indicated for the first-line treatment of patients with locally advanced or metastatic carcinoma of the esophagus or HER2 negative gastroesophageal junction adenocarcinoma (tumor center 1 to 5 centimeters above the gastroesophageal junction) that is not amenable to surgical resection or definitive chemoradiation, in adults whose tumors express PD-L1 with a CPS ≥ 10, as determined by a validated test.	**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)
2.	Dupixent 300 mg Solution for Injection in Pre-filled Syringe [Dupilumab 150mg/mL]	**INDICATION :** Dupixent is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO). Dupixent is indicated as maintenance therapy for oral corticosteroid dependent asthma. **POSOLOGY** : The recommended dose of Dupixent for adults and adolescents (12 years of age and older) is: • An initial dose of 400 mg (two 200 mg injections followed by 200 mg given every other week administered as subcutaneous injection. • For patients with severe asthma and who are on oral corticosteroids or for patients with severe asthma and co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid severe chronic rhinosinusitis with nasal polyposis, an initial dose of 600 mg (two 300 mg injections), followed by 300 mg every other week administered as subcutaneous injection. Patients receiving concomitant oral corticosteroids may reduce their steroid dose once clinical improvement with dupilumab has occurred. Steroid reductions should be accomplished gradually. Dupixent is intended for long-term treatment. The need for continued therapy should be considered at least on an annual basis as determined by physician assessment of the patient's level of asthma control.	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	SURVANTA INTRATRACHEAL SUSPENSION [Beractant (Phospolipids)-Lung 25mg/ml]	**POSOLOGY** : Instillation in Spontaneously Breathing Patients Intubation Surfactant Extubation (INSURE) Following intubation and catheterization as described above, place the infant in a neutral position and gently inject the dose as a single bolus over 1 to 3 minutes in the delivery room or later after admission to the neonatal unit. After instillation, use a bagging technique and proceed to extubation and CPAP as clinically indicated.	**ABBVIE SDN. BHD.** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>4.</td><td>NAROPIN 7.5MG/ML-20ML POLYAMP (BLISTER PACK) SOLUTION FOR INJECTION

[Ropivacaine HCL 7.5mg/ml]</td><td>
INDICATION :

<u>Naropin 7.5 mg/ml:</u>

Surgical anaesthesia
• Major nerve block

POSOLOGY :
(For adult and children >12 years dosing only)
<table>
<tr><td></td><td>Conc.</td><td>Volume</td><td>Dose</td><td>Onset</td><td>Duration</td></tr>
<tr><td></td><td>mg/ml</td><td>ml</td><td>mg</td><td>min</td><td>hours</td></tr>
<tr><td colspan="6">SURGICAL ANAESTHESIA</td></tr>
<tr><td>Major Nerve Block

(e.g. brachial plexus)</td><td>7.5</td><td>30-40</td><td>225-300</td><td>10-25</td><td>6-10</td></tr>
<tr><td colspan="6">(3) The dose for a major nerve block must be adjusted according to site of administration and patient status. Supraclavicular brachial plexus blocks may be associated with a higher frequency of serious adverse reactions, regardless of the local anaesthetic used.</td></tr>
</table>
</td><td>ASPEN MEDICAL PRODUCTS MALAYSIA SDN. BHD.
Unit 1302A. Level 13A, Uptown 1, 1 Jalan SS21/58, Damansara Uptown, 47400 Petaling Jaya, Selangor.</td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	ERAXIS 100MG FOR INJECTION [Anidulafungin 100mg]	**INDICATION :** Treatment of invasive candidiasis, including candidemia, in adult and in paediatric patients aged 1 month to <18 years old. **POSOLOGY :** Paediatric population (1 month to < 18 years) (dosing and treatment duration) A single loading dose of 3.0 mg/kg (not to exceed 200 mg) should be administered on Day 1 followed by a daily maintenance dose of 1.5 mg/kg (not to exceed 100 mg) thereafter. Duration of treatment should be based on the patient's clinical response. In general, antifungal therapy should continue for at least 14 days after the last positive culture. The safety and efficacy of anidulafungin have not been established in neonates (<1 month old).	**PFIZER (MALAYSIA) SDN. BHD.** Level 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
6.	Convidecia (Trade Mark) Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) Solution for Injection [Each 0.5mL contains ≥ 4×10^{10} vp of replication-defective recombinant human type 5 Adenovirus expressing S protein of SARS-CoV-2]	**POSOLOGY :** <u>Individuals 18 years of age and older:</u> Single dose. Each dose contains 0.5 mL liquid injection, supplied in a single-dose glass vial or three-dose glass vial. A booster dose (0.5ml) may be administered at least 3-6 months after the first single 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). <u>Pediatric Population:</u> The safety and efficacy data in children and adolescent (less than 18 years old) have not yet established. No data available. <u>Elderly Population (>60 years and above):</u> The safety and efficacy data of people aged 60 years and above are limited in the clinical trials. Women in childbearing age: The data collected in clinical trials for women who have unintended pregnancy after Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) vaccination is very limited. It is not enough to assess the risk of adverse pregnancy outcomes (including spontaneous abortion) after vaccination with Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector). <u>Method of administration</u> A single dose for intramuscular injection in the deltoid muscle of the upper arm.	**SOLUTION BIOLOGICS SDN. BHD.** PT 13796 Jalan Tekno Usahawan 2, Technology Park Malaysia, 57000 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<u>Instruction for use</u> A disposable medical grade syringe is used to extract the liquid in the vial. After emptying air bubbles, the vaccine can be injected in the deltoid muscle of the upper arm. The vaccine should be checked if the packaging container, label, appearance and expiry date meet the requirements before injection. It should not be used under following circumstances: crack on the vaccine vial or syringe, presence of visible particles, discoloration, falling off label or expired vaccine. Once the vaccine is opened, it should be used immediately. Each dose of vaccine should be used up at one time and not divided into multiple uses.	