Maklumat tambahan indikasi

Tahun 2022

Products Approved For Additional Indication (DCA 373 – 2 June 2022)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Janssen COVID-19 Vaccine Suspension for Injection [Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein (Ad26.COV2-S), not less than 8.92 $\log_{10}$ infectious units (Inf.U)]	**POSOLOGY :** Individuals 18 years of age and older Primary vaccination Janssen COVID-19 Vaccine is administered as a single-dose of 0.5 mL by intramuscular injection only. Homologous booster dose A booster dose (second dose) of 0.5 mL of Janssen COVID-19 Vaccine may be administered intramuscularly at least 2 months after the primary vaccination in individuals 18 years of age and older (see also sections 4.4, 4.8 and 5.1). The decision when and for whom to implement a booster dose of Janssen COVID-19 Vaccine should be based on official recommendations. Heterologous booster dose A booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered as a heterologous booster dose following completion of primary vaccination with an approved mRNA COVID-19 vaccine (see section 5.1). The dosing interval for the heterologous booster dose is the same as that authorised for a booster dose of the vaccine used for primary vaccination (see also sections 4.4, 4.8 and 5.1). The decision when and for whom to implement a booster dose of Janssen COVID-19 Vaccine should be made based on available vaccine effectiveness data, taking into account limited safety data (see section 5.1) Paediatric population The safety and efficacy of Janssen COVID-19 Vaccine in children and adolescents (less than 18 years of age) have not yet been established. No data are available. Elderly No dose adjustment is required in elderly individuals ≥ 65 years of age.	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor.

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2.	Vaxzevria 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 Vaxzevria 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 Vaxzevria with other COVID-19 vaccines to complete the vaccination course. Individuals who have received the first dose of Vaxzevria should receive the second dose of Vaxzevria to complete the vaccination course. **A booster dose of 0.5 ml Vaxzevria may be administered at least 3 months after the second dose of Vaxzevria or another authorised COVID-19 vaccine (see sections 4.8 and 5.1) 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>Elderly population</u> No dose adjustment is required. See also section 4.4 and 5.1. <u>Paediatric population</u> The safety and efficacy of COVID-19 Vaccine AstraZeneca in children and adolescents (less than 18 years of age) have not yet been established. No data are available. <u>Method of administration</u> COVID-19 Vaccine AstraZeneca is for intramuscular injection only, preferably in the deltoid muscle of the upper arm. Do not inject the vaccine intravascularly, subcutaneously or intradermally. The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products. For precautions to be taken before administering the vaccine, see section 4.4. For instructions on handling and disposal, see section 6.6.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

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3.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION:** KEYTRUDA, in combination with chemotherapy with or without bevacizumab, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) 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.

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4.	DYSPORT POWDER FOR INJECTION [Clostridium Botulinum Toxin Type A – haemagglutinin complex]	**INDICATION :** Dysport is indicated for symptomatic treatment of focal spasticity of: • Upper limbs in adults • Lower limbs in adults affecting the ankle joint due to stroke or traumatic brain injury (TBI) • Dynamic equinus foot deformity in ambulant paediatric cerebral palsy patients, two years of age or older. • **Upper limbs in paediatric cerebral palsy patients, two years of age or older.** Dysport is indicated in adults for symptomatic treatment of: • Spasmodic torticollis • Blepharospasm • Hemifacial spasm • Axillary hyperhidrosis. • Moderate to severe glabellar lines Dysport is indicated for the temporary improvement in the appearance of moderate to severe lateral canthal lines (crow's feet lines) seen at maximum smile in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient. **POSOLOGY :** Focal spasticity in paediatric cerebral palsy patients, two years of age or older Dysport maximum total doses per treatment session and minimum times before retreatment	**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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[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
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<tr><th>Limb</th><th>Maximum total dose of Dysport to be administered per treatment session</th><th>Minimum time before retreatment should be considered</th></tr>
<tr><td>Single lower limb
Both lower limbs</td><td>15 units/kg or 1000 units*
30 units/kg or 1000 units*</td><td>No sooner than 12 weeks</td></tr>
<tr><td>Single upper limb
Both upper limbs</td><td>16 units/kg or 640 units*
21 units/kg or 840 units *</td><td>No sooner than 16 weeks</td></tr>
<tr><td>Upper and lower limbs</td><td>30 units/kg or 1000 units*</td><td>No sooner than 12-16 weeks</td></tr>
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*whichever is lower
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