Maklumat tambahan indikasi

Tahun 2022

Products Approved For Additional Indication (DCA 375 – 4 August 2022)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Symvenu 1.5mg Hard Capsules [Cariprazine hydrochloride 1.645mg (equivalent to 1.5mg free base)] Symvenu 3mg Hard Capsules [Cariprazine hydrochloride 3.270mg (equivalent to 3mg free base)]	**INDICATION :** Symvenu is indicated for - treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adult patients. **POSOLOGY** : Depressive episodes associated with Bipolar I Disorder (Bipolar Depression) The starting dose of cariprazine is 1.5 mg once daily. Depending upon clinical response and tolerability, the dosage can be increased to 3 mg once daily on Day 15. Maximum recommended dosage is 3 mg once daily.	**MITSUBISHI TANABE PHARMA MALAYSIA SDN. BHD.** Suite 8.3, Level 8, Wisma UOA Damansara II, No. 6, Changkat Semantan, 50490 Bukit Damansara, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Lorviqua 25 mg Film-Coated Tablets [Lorlatinib 25 mg] Lorviqua 100 mg Film-Coated Tablets [Lorlatinib 100 mg]	**INDICATION:** LORVIQUA as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. **POSOLOGY :** Treatment with lorlatinib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. <u>ALK testing</u> Detection of ALK positive NSCLC is necessary for selection of patients for treatment with lorlatinib because these are the only patients for whom benefit has been shown. Assessment for ALK positive NSCLC should be performed by laboratories with demonstrated proficiency in the specific technology being utilized. Improper assay performance can lead to unreliable test results.	**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)
3.	Spikevax 0.20 mg/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) [mRNA1273 1 dose (0.5ml) contains 100µg of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles) [Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.)]	**INDICATION:** Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older. The use of this vaccine should be in accordance with official recommendations. **POSOLOGY :** Individuals **12** years of age and older Spikevax is administered as a course of 2 doses (0.5 mL each). It is recommended to administer the second dose 28 days after the first dose. There are no data available on the interchangeability of Spikevax with other COVID-19 vaccines to complete the vaccination course. Individuals who have received the first dose of Spikevax should receive the second dose of Spikevax to complete the vaccination course. Paediatric population The safety and efficacy of Spikevax in children and adolescents less than **12** years of age have not yet been established. No data are available. Elderly population No dosage adjustment is required in elderly individuals ≥65 years of age.	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.