

Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 359 – 15 Jun 2021)

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
1.	COMIRNATY Concentrate for Dispersion for Injection [BNT162b2 1 dose (0.3ml) contains 30 µg of modRNA [Single-stranded, 5'-capped mRNA formulated as an RNA-lipid nanoparticle (LNP) of nucleoside-modified mRNA (modRNA)]	<p>INDICATION :</p> <p>Comirnaty is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older.</p> <p>The use of this vaccine should be in accordance with official recommendations.</p> <p>POSODOLOGY: <u>Individuals 12 years of age and older</u></p> <p>Comirnaty is administered intramuscularly after dilution as a course of 2 doses (0.3 mL each). It is recommended to administer the second dose 3 weeks after the first dose.</p> <p>There are no data available on the interchangeability of Comirnaty with other COVID-19 vaccines to complete the vaccination course. Individuals who have received 1 dose of Comirnaty should receive a second dose of Comirnaty to complete the vaccination course.</p> <p><u>Paediatric population</u></p> <p>The safety and efficacy of Comirnaty in children aged less than 12 years of age have not yet been established. Limited data are available.</p>	<p>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.</p>