

Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 364 – 1 Oktober 2021)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	<p>CoronaVac Suspension for Injection SARS-CoV-2 Vaccine (Vero Cell), Inactivated</p> <p>[Inactivated SARS-CoV-2 virus (CZ02 strain) (Vero cell)]</p> <p>CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated</p> <p>[Inactivated SARS-CoV-2 virus (CZ02 strain) (Vero cell)]</p>	<p>INDICATION :</p> <p>CoronaVac is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2, 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:</p> <p><u>Individuals 18 years of age and older</u> 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.</p> <p><u>Children and adolescent 12 -17 years of age</u> 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.</p> <p><i>It has not been determined whether this product requires booster immunization.</i></p> <p><u>Elderly population</u> No dosage adjustment is required in elderly individuals ≥ 60 years of age.</p> <p><i>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.</i></p>	<p>PHARMANIAGA LIFESCIENCE SDN. BHD. Lot 7, Jalan PPU 3, Taman Perindustrian Puchong Utama, 47100 Puchong, Selangor.</p>