FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT COVILO VACCINE (also known as COVID-19 Vaccine Sinopharm)

Q1: What vaccine is being registered?

A1: The Drug Control Authority (DCA) in its 361st meeting has granted **COVILO Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated** (Product Registration Holder: Duopharma Sdn. Bhd.; Manufacturer: Beijing Institute of Biological Products Co. Ltd, CNBG, Sinopharm China) a CONDITIONAL REGISTRATION on 16th July 2021.

Each vial of COVILO contains 0.5ml (single dose).
Each dose (0.5ml) of COVILO contains 6.5U (ranged from 3.9-10.4 units) of inactivated SARS-CoV-2 antigen (HB02 strain).

Q2: What are the conditions of the registration?

A2: Since the registration application is via "Conditional Registration of Pharmaceutical Products during Disaster", the approval is based on rolling submission of the latest data. The Product Registration Holder (PRH) will need to ensure all outstanding documents are to be submitted and deemed satisfactory by National Pharmaceutical Regulatory Agency (NPRA) according to the timeline given.

Apart from that, the PRH is required to monitor the safety profile of the registered vaccine and inform NPRA soonest possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP) as well as submitting Monthly Safety Summary Report to NPRA.

The validity of this conditional approval is one (1) year. During this period, the DCA will periodically be updated with all necessary information related to the quality, safety and efficacy of this vaccine. The conditional registration can be revoked if the conditions are not fulfilled by the PRH or if the benefit over risk of the vaccine is no longer deemed beneficial.

Q3: Why is COVILO granted a conditional registration?

A3: Clinical studies for COVILO are currently still on-going. The current interim analysis provided show a positive benefit over risk and hence making this available to the nation. However, further monitoring of the efficacy and safety will be needed in order to ensure that the benefit-risk balance of this vaccine remains positive.

Q4: Who can be given COVILO?

A4: COVILO is indicated for the active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 - 59 years of age.
The vaccine efficacy of this product for adults in 18-59-year-old cohort have been shown based on the interim report of the international Phase III clinical trial, in which, the proportion of older adults (≥60 years old) was low (2.01%).

The use of this vaccine should be in accordance with the recommendations by the Ministry of Health Malaysia.

Q5: Who can't be given COVILO?

A5: COVILO should not be given to individuals;

a. who are known to have allergic reactions to any of the ingredients in the vaccine (Aluminium hydroxide, disodium hydrogen phosphate, sodium chloride, sodium dihydrogen phosphate);
b. who have allergic reactions with vaccines before (angioneurotic edema [swelling of the face, eye, lips or throat], dyspnoea [shortness of breath], etc)
c. with uncontrolled epilepsy or other progressive nervous system diseases, and with a history of Guillain-Barré syndrome;

The second dose of the vaccine **should not be given** to individuals who have a severe allergic reaction (e.g. acute anaphylaxis, angioedema, dyspnoea [shortness of breath]) after the first dose of this vaccine.

Q6: Can the following populations receive COVILO?

A6: At the moment, there are insufficient clinical evidence to support vaccination in these population: Impaired immune function (individuals with malignant tumour, nephrotic syndrome, AIDS) including those receiving immunosuppressant therapy. Use of COVILO in these individuals should be in consideration of a potentially lowered immune response. Human immunoglobulin injections should be given at least one-month interval before or after the administration of the vaccine to avoid lowered immune response.

However, these recommendations may change as more clinical data is obtained. Please speak to your doctor to identify if you may be a suitable candidate to receive the vaccine.

Q7: If I have the following conditions, or receiving or have received these treatments, can I receive the vaccine?

A7: Please consult your doctor if you;

- have acute diseases, acute onset of chronic diseases (other diseases / health conditions) and fever
- have diabetes, those with a history or a family history of convulsions, epilepsy, encephalopathy (disease that affects the brain) or mental illness
- have decrease in platelets or clotting disorders because of the risk of bleeding which may occur during intramuscular administration of the vaccine
- had a previous history of COVID-19 infection, had previously received another COVID-19 vaccine (whether during an immunisation program or was involved as a subject in a COVID-19 clinical study) or previously received passive antibodies therapy for COVID-19.

You may receive the vaccine even if you have the above conditions. However, please speak with your doctor before deciding if you are a suitable candidate.

Q8: How is COVILO given?
A8: COVILO should be injected into the deltoid muscle of the upper arm as a course of 2 doses (0.5mL each). The second dose is to be taken 21 to 28 days after the first dose.

Q9: How well does COVILO prevent COVID-19?
A9: Based on the interim analysis of the Phase III clinical trial conducted in the United Arab Emirates (Abu Dhabi, Sharjah), Kingdom of Bahrain, and many other countries/regions, the vaccine was 78.89% (95%CI: 65.79-86.97) effective in preventing symptomatic COVID-19 disease following completion of 2 doses of the vaccine regime. This fulfilled the efficacy standard as recommended by WHO, where the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%, and the lower bound of confidence interval (CI) should be >30%. More data is expected from other ongoing Phase III trials in other countries on a rolling review basis.

Q10: How long will COVILO provide protection?
A10: As the clinical trial is still currently ongoing, no data is available on the duration of protection that the vaccine will provide. This however will be made known once updated data is available.

Q11: Can people who have already had COVID-19 get COVILO?
A11: Available data indicate that COVILO is safe when given in people with evidence of prior COVID-19 disease. Since previously infected individuals can be at risk of COVID-19 (i.e. reinfection), vaccination may be offered to them. However, please speak with your doctor before deciding if you are a suitable candidate.

Q12: Can pregnant or breastfeeding women receive COVILO?
A12: Limited experience exists with use of this vaccine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or postnatal development. Administration of this vaccine in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus. In addition, it is unknown whether the vaccine is excreted in human milk.

Q13: Can elderly receive COVILO?
A13: At present, the evidence of the protective efficacy and safety of this product on people aged ≥ 60 has not been obtained. Therefore currently the vaccine is only indicated for people aged 18 to 59 years of age.

Q14: Can children receive COVILO?
A14: Currently in Malaysia, the vaccine is indicated for individuals 18-59 years old only. This is because there is not enough data yet to determine the effectiveness and safety of this vaccine in those under 18 years old. Hence children below the age of 18 should not take the vaccine until further data is made available.

Q15: What are the side effects of COVILO?
A15: COVILO can cause the following side effects:

- Very common side effects (may affect more than 1 in 10 people): pain at injection site, headache.
- Common side effects (may affect up to 1 in 100 people): fever, fatigue, muscle pain, joint pain, cough, shortness of breath, nausea, diarrhoea, itchiness
- Uncommon side effects (may affect up to 1 in 1,000 people): redness, swelling, hardening at injection site, rash, dizziness, eating disorder (anorexia), vomiting, sore throat, difficulty swallowing food or drinking, running nose, constipation, allergic reaction
- Rare side effects (may affect up to 1 in 10,000 people): acute allergic reaction, lethargy, drowsiness, difficulty falling asleep, sneezing, common cold, blocked nose, dry throat, influenza(flu), loss of sensation, limb pain, palpitations, abdominal pain, acne, feeling pain around the eyes, ear discomfort, swollen lymph nodes.
- Very rare side effects (may affect less than 1 in 10,000 people): chills, loss of taste, numbness or tingling sensation, tremor, difficulty focusing, bleeding from the nose, asthma, throat irritation, tonsils inflammation, physical discomfort, neck pain, jaw pain, feeling of lump at the neck, mouth ulcers, toothache, gastric, faecal discoloration, blurred vision, eye irritation, earache, tension, change in blood pressure, uncontrolled urine leakage, delayed menstruation.

Recipient will be monitored 15-30 minutes after the administration of this vaccine at the vaccination centre. Medicines such as epinephrine and equipment should be available for emergency treatment in the event of an occasional severe allergic reaction.

During marketing of COVILO in Malaysia, NPRA will monitor its use to ensure effectiveness and safety. Please inform your healthcare providers or report any side effects to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Q16: What should I do after I am vaccinated?
A16: All individuals should continue to follow the country's SOP. Practice the 3Ws (**Wash**, **Wear**, **Warn**) and avoid the 3Cs (**Crowded** space, **Confined** space, **Close** conversation).

For further information regarding **COVILO Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated***, please refer to the Package Insert and Patient Information Leaflet.*

https://quest3plusbackend.bpfk.gov.my/front-end/attachment/17051/pharma/541720/541720_20210716_151918_.pdf

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