

DISCLAIMER: THIS PRODUCT IS APPROVED UNDER MALAYSIA CONDITIONAL REGISTRATION FOR PHARMACEUTICAL PRODUCTS DURING DISASTER GUIDELINE. THE ADMINISTRATION OF THE PRODUCT IS PURELY BASED ON INDIVIDUAL'S PREFERENCE.

## COVILO Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated

Inactivated SARS-CoV-2 virus (19nCoV-CDC-Tan-HB02 strain) (Vero cell)

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allergic reaction to other vaccines in the past.

- if you have nervous system diseases such as uncontrolled epilepsy (seizure) and Guillain-Barre syndrome.

### *Pregnancy and lactation*

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you receive this vaccine.

### *Children and adolescents*

COVILO is not recommended for children aged under 18 years as limited safety and efficacy data are available.

### *Elderly adults 60 years old and above*

COVILO is not recommended for elderly adults 60 years old and above as limited safety and efficacy data are available.

### *- Before you start to use it*

Talk to your doctor before taking COVILO if:

- You have ever had a severe allergic reaction to other vaccines in the past or after you were given the first dose of COVILO.
- You have blood-clots disorders or high risk of bleeding.
- You have a weakened immune system due to diseases such as cancer, nephrotic syndrome or HIV infection.
- You have taken or need to take human immunoglobulins. There should be an interval of

at least one month apart between the use of immunoglobulins and COVILO vaccine.

- You have acute diseases, acute onset of chronic diseases and fever. Your doctor may need to delay your vaccination.
- You currently have diabetes or have a history or family history of seizures, epilepsy, encephalopathy or mental illness.

As with any vaccines, the 2-dose vaccination course of COVILO may not fully protect all those who receive it and it is not known how long you will be protected.

### *- Taking other medicines*

Tell your doctor if:

- You are taking medicines that affects your immune system such as immunosuppressants, corticosteroid or cancer medicines.
- You have recently taken any vaccines or medicines.
- No interaction studies between COVILO and other drugs or vaccines have been performed.

**COVILO does not contain alcohol or any preservatives**

### **How to use COVILO**

#### *- How much to use*

COVILO is given as an injection of 0.5ml into the upper part of your arm. You will receive 2 injections, given at least 21-28 days apart.

After injecting the vaccine, you

### What COVILO is used for

COVILO is a vaccine used to prevent COVID-19 caused by SARS-CoV-2 virus.

COVILO is given to adults of 18 to 59 years of age.

A booster dose (0.5mL) of COVILO may be administered at least 3-6 months after the second dose.

### How COVILO works

The vaccine stimulates the immune system (the body's natural defenses) to produce its own antibodies and blood cells that work against the virus. This will help to increase your protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

### Before you use COVILO

#### *- When you must not use it*

Do not take COVILO

- if you have an allergy to COVILO or any of the other ingredients listed at the end of this leaflet.
- if you have ever had a severe

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will be observed for at least 15 minutes in case of allergic reactions.

There are currently no data available on the interchangeability of COVILO with other COVID 19 vaccines. You should receive the second dose of the same vaccine after 21-28 days from the first dose to complete the vaccination course.

If you have any further questions on the use of COVILO, ask your doctor, pharmacist or nurse.

- *If you forget to use it*

If you missed the second dose, consult your doctor or pharmacist for advice.

- *If you use too much (overdose)*

Immediately contact your doctor for advice, or go to the Emergency Department of the nearest hospital, if you think that you or anyone else may have taken too much of this vaccine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

### **While you are using it**

- *Things you must do*

Always follow your doctor's instructions carefully.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking COVILO.

- *Things you must not do*

Concomitant administration of COVILO with other vaccines has not been studied. Therefore, do not take any new medicines after receiving COVILO without consulting your doctor.

- *Things to be careful of*

#### *Driving and using machines*

There is no study available on the effects of COVILO on driving and usage of machines. Be careful driving or operating machinery until you know how COVILO affects you. Wait until these effects have worn off before you drive or use any machines.

### **Side effects**

All medicines including COVILO can cause side effects, although not everyone experience them. You may need medical attention if you experience the side effects.

Contact your doctor or pharmacist immediately if you experience any side effects after taking this vaccine.

Side effects for both primary vaccination schedule and booster dose that occurred during clinical trials were as follows:

*Very common: may affect more than 1 in 10 people*

-injection site: pain  
-headache

*Common: may affect up to 1 in 100 people*

-fever  
-fatigue  
-joint pain

-muscle pain  
-cough  
-diarrhea  
-shortness of breath  
-rashes  
-nausea

*Uncommon: may affect up to 1 in 1,000 people*

-injection site: redness, swelling, rashes  
-dizziness  
-vomiting  
-running nose  
-constipation  
-difficult swallowing  
-loss of appetite  
-pain at the throat

*Rare: may affect up to 1 in 10,000 people:*

-injection site: red patches on skin  
-acute allergic reaction  
-tiredness  
-drowsiness  
-difficulty falling asleep  
-sneezing  
-nose block  
-cold  
-loss of sensation  
-limb pain  
-palpitations  
-abdominal pain  
-abnormal skin lesion  
-acne  
-pain in the eye  
-ear discomfort  
-abnormal size of lymph nodes

*Very rare: may affect up to 1 in 100,000 people:*

-chills  
-loss of taste  
-burning or prickling sensation of the limbs  
-nose bleed  
-asthma  
-throat irritation

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-neck or jaw pain  
-mouth ulcers  
-toothache  
-blurred vision  
-hypertension or hypotension  
-delayed menstruation  
-urinary incontinence

If any of the side effects get serious, tell your doctor.

If you experience any side effects, including those not listed in this leaflet, talk to your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <http://www.npra.gov.my> (Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

### **Storage and disposal of COVILO**

#### **- Storage**

Keep this medicine out of the sight and reach of children.

Store in a refrigerated condition of 2°C - 8°C. Store in original packaging and protect from light.

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

Avoid freezing the vaccine. Mix well before use. The vaccine

should be used immediately after opening.

Avoid using disinfectant to contact the vaccine when the protective cap is pulled off and injection.

Do not use the vaccine if there are cracks, spots, stains, scratches, blurred label on the container, or the presence of foreign particulates.

#### **- Disposal**

Do not throw away any vaccine via wastewater or household waste. Any unused vaccine material should be disposed of in accordance with local requirements.

These measures will help protect the environment.

### **Product Description**

#### **- What it looks like**

COVILO is a semi-transparent suspension with slightly white color, which could be layered due to precipitation, that can be easily dispersed by shaking.

Each dose of vial contains 0.5ml of 3.9 – 10.4 units of inactivated SARS-CoV-2 antigen and 0.3-0.6 mg/ml aluminium hydroxide adjuvant.

The Vaccine Vial Monitors (VVM) are on the label of Beijing Institute of Biological Products

Co., Ltd. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level. The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded. As indicated in the VVM graphic (Graphic 1) in the end of the package information leaflet.

#### **- Ingredients**

Active ingredient

SARS-CoV-2, 19nCoV-CDC-Tan-HB02 strain (inactivated)

Inactive ingredients:

Aluminium hydroxide, disodium hydrogen phosphate, sodium chloride, sodium dihydrogen phosphate

#### **- MAL number**

MAL21076098AZ

**Manufacturer and Batch Release Site:**

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Beijing Institute of Biological Products Co., Ltd.

No. 6&9 Bo'xing 2nd Road,  
Economic-Technological  
Development Area, Beijing,  
100176, P.R.China.

### **Product Registration Holder**

DUOPHARMA (M) SDN. BHD.

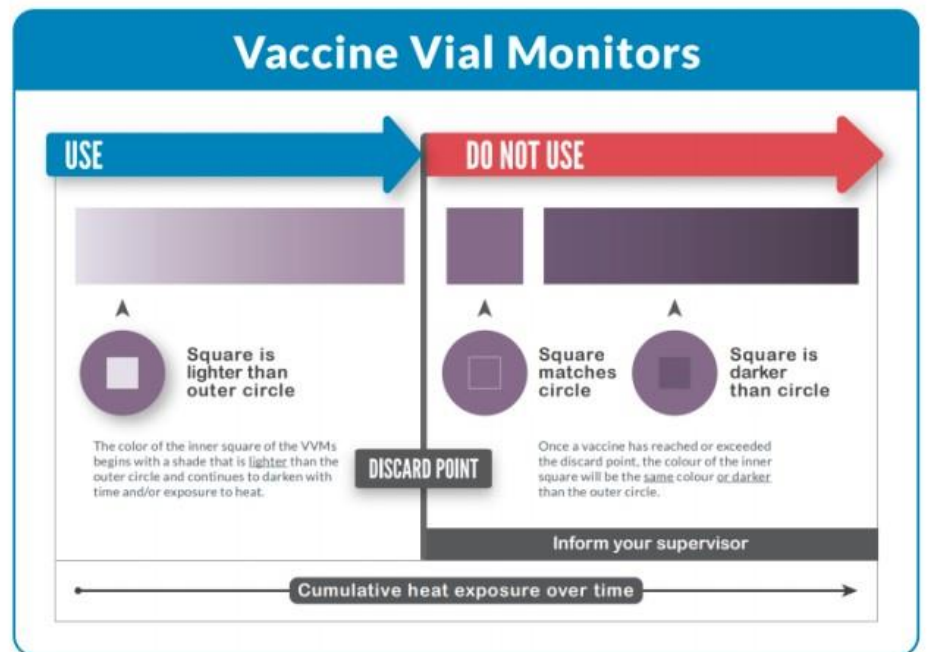
Lot. 2599, Jalan Seruling 59,  
Kawasan 3, Taman Klang Jaya,  
41200 Klang, Selangor Darul  
Ehsan, Malaysia.

### **Date of Revision**

03 March 2022

### **Serial Number**

NPRA(R3/01)15022022/0163



**Graphic 1: Vaccine Vial Monitors (VVM)**