

**SCHEDULING STATUS**

S4

**PROPRIETARY NAME** COVID-19 VACCINE MC PHARMA**(AND DOSAGE FORM)** INTRAMASCULAR INJECTION**COMPOSTION**

The COVID-19 VACCINE MC PHARMA SARS-CoV-2 Vaccine (Vero Cell), inactivated is formulated with SARS-CoV-2 strain, which is inoculated on the Vero cells for culturing, virus harvesting, [2]-propiolactone-inactivation, concentration and purification, then adsorbed with aluminum adjuvant to form the liquid vaccine.

**Active composition:** SARS-CoV-2 (inactivated)**Excipients:** Disodium hydrogen phosphate (dodecahydrate), Sodium chloride, Sodium dihydrogen phosphate (monohydrate), Aluminum hydroxide adjuvant**PHARMACOLOGICAL CLASSIFICATION**

A 30.5 Other

ATC code: J07BX03

**PHARAMACOLOGICAL ACTION**

SARS-CoV-2 Vaccine (Vero Cell), Inactivated

Please read the instructions carefully and use under the guidance of a physician

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Pretoria  
18H20

**INDICATIONS:**

The antibodies against the SARS-CoV-2 can be produced after vaccination, to prevent the COVID-19 disease.

This product is used for adults and children over 18 years old, particularly for medical personnel and those in close contact with the virus.

**CONTRAINDICATION:**

This vaccine is strictly prohibited in the following cases:

- (1) Individuals who are allergic to any component (active, excipients) of this product, or those who have allergic reactions with this vaccine before.
- (2) Individuals who have serious chronic disease or history of hypersensitivity.
- (3) Vaccination should be postponed if individuals have fever or during the acute phase of disease.  
because of the risk of bleeding which may occur during intramuscular administration of the vaccine.
- (4) Like all vaccines, this product may not have 100% preventive effect for vaccine.
- (5) Do not use disinfectant to contact the vaccine when the protective cap is pulled off and injection.
- (6) This vaccine should be used immediately after opening.
- (7) Do not use after the expiration date stated on the box and on the label.

Keep away from reach of children

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## **WARNINGS**

(1) Intravascular injection is strictly prohibited.

(2) Drugs and equipment such as epinephrine should be available for emergency treatment in the event of an occasional severe allergic reaction. The vaccine should be watched for at least 30 minutes after vaccination.

(3) This vaccine should be used with caution if:

- have blood disorders such as decrease in platelets (thrombocytopenia) or clotting disorders.
- are taking a treatment that suppresses your immune defence or if you present with immune deficiency, the immune response to the vaccine may be reduced. In such cases it is recommended to postpone vaccination until the end of the treatment or to make sure the subject is well protected. If you have chronic immune deficiency, this vaccine may also be recommended even though the underlying disease may cause a limited immune response.
- You have uncontrolled epilepsy and other progressive neurological disorders.

Special Patient Group (Consult a medical practitioner)

- Elderly or geriatric patients
- Immunocompromised
- Pregnant and lactating mothers

## **DOSAGE AND DIRECTIONS FOR USE**

### **DOSE**

Each vial contains 6.5U/0.5 ml of product for each administration by intramuscular injection, each dose contains 6.5U/0.5 ml of inactivated SARS-CoV-2 antigen.

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## Immunization Program

This vaccine will be administered by a healthcare professional of national health authorities and CDC in accordance with the national immunization program and strategies.

Method of Administration: The recommended administration is through intramuscular route, the injection into a muscle will be preferably performed in the upper part of the arm. Immunization

Program and Dosage: Two successive doses at an interval of 2-4 weeks, each dose is 0.5ml.

The immune persistence study of this vaccine has not been conducted currently.

## **SIDE EFFECTS AND SPECIAL PRECAUTIONS**

The occurrence rate for ADRs (CIOMS recommendation) can be presented as:

- (1) Very common: Pain at the injection site;
- (2) Common: Transient fever, fatigue, headache, diarrhea; redness, swelling, itching, and hardening at the injection site;
- (3) Uncommon: Skin rash at the injection site; nausea and vomiting, itching at the non-injection site, muscle pain, arthralgia, drowsiness, dizziness, etc.
- (4) No vaccine-related serious adverse reaction was observed.

If there are any adverse reactions not mentioned above during the use of this vaccine, please inform the physician in time.

## **Drug Interaction**

- (1) The clinical trial results of this vaccine in combination with other routine vaccines have not yet been provided.

(2) If any drugs are being taken or recently taken, including over the counter (OTC), please inform the physician in time.

**IDENTIFICATION:**

The product is a semi-transparent turbid suspension with slight white colour, which could be layered due to precipitation, and the precipitation can be easily dispersed by shaking.

**PRESENTATION:**

Pack Size Description 1 Vial (0.5 ml)

1 Vial / box.

1 dose / vial per box

EXP. 12 months (Tentatively)

**STORAGE:**

Store and transport in a refrigerated (2°C-8°C) condition, protect from light. Do not freeze.

**REGISTRATION NUMBER:**

56/30.5/0795

**MANUFACTURER:**

Bulk Manufacturer – Beijing Institute of Biological product Co Ltd

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**MARKETING AUTHORISATION HOLDER:**

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