

LHC Pharmaceuticals (Pty) Ltd  
COVID-19 VACCINE LHC  
Suspension for Injection  
Inactivated SARS-CoV-2 antigen 4 µg/0.5 ml

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

**S4**

#### **Covid-19 Vaccine LHC**

4 µg/0.5 ml dose: Suspension for injection

Active substance Inactivated SARS-CoV-2 antigen

Sugar free

#### **Read all of this leaflet carefully before you are given Covid-19 Vaccine LHC**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

#### **What is in this leaflet**

1. What Covid-19 Vaccine LHC is and what it is used for
2. What you need to know before you are given Covid-19 Vaccine LHC
3. How Covid-19 Vaccine LHC is given.
4. Possible side effects
5. How to store Covid-19 Vaccine LHC
6. Contents of the pack and other information

#### **1. What Covid-19 Vaccine LHC is and what it is used for**

Pharmacotherapeutic group: vaccines, other viral vaccines, ATC code: J07BX03.

Covid-19 Vaccine LHC is a vaccine and is given to stimulate the body to produce antibodies to SARS-CoV-2 virus, the cause of COVID-19 and thus help to protect against COVID-19 infection.

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### 2. What you need to know before you are given Covid-19 Vaccine LHC

#### **Covid-19 Vaccine LHC should not be administered to you :**

- if you are hypersensitive (allergic) to inactivated SARS-CoV-2 antigen cultured in Vero Cell or any of the other ingredients of Covid-19 Vaccine LHC (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away if you have an allergic reaction. It can be life-threatening.
- If you have serious chronic disease or history of hypersensitivity.
- if you have a severe illness with high fever.

#### **Warnings and precautions**

Talk to your doctor, pharmacist, or nurse before you are given the vaccine if you have:

(1) have blood disorders such as decrease in platelets (thrombocytopenia) or clotting disorders because of the risk of bleeding which may occur during intramuscular administration of the vaccine.

(2) are taking immunosuppressants, in such cases it is recommended to postpone vaccination until the end of the treatment to make sure you are well protected.

(3) if you have chronic immune deficiency, you may still be vaccinated even though the underlying disease may cause a limited immune response.

(4) if you have uncontrolled epilepsy and other progressive neurological disorders.

Like all vaccines, this product may not have 100% preventive effect against the disease.

#### Children

Covid-19 Vaccine LHC is not recommended for children or persons under 18 years.

#### **Other medicines and Covid-19 Vaccine LHC**

Tell your doctor or pharmacist if you are using, have recently used or might use any other

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medicines or have recently received any other vaccine.

### **Pregnancy, breastfeeding and fertility**

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

There is no experience with use of the Covid-19 Vaccine LHC in pregnant or breast feeding women

If after vaccination, you find that you are pregnant, you must report this to your doctor or pharmacist or nurse, to allow them to monitor your pregnancy.

### **Driving and using machines**

Covid-19 Vaccine LHC has no or negligible influence on the ability to drive and use machines. However, some of the adverse reactions mentioned under section 4 “Possible side-effects” may temporarily affect the ability to drive or use machines. Do not drive or operate machinery until you are sure that you are not affected

### **Covid-19 Vaccine LHC contains**

Sodium Chloride, Disodium Hydrogen Phosphate, Sodium Dihydrogen Phosphate and Aluminium Hydroxide

### **3. How Covid-19 Vaccine LHC is given.**

You will receive 2 injections, given at least 21-28 days apart.

If you receive one dose of Covid-19 Vaccine LHC, you should receive a second dose of the same vaccine at least 21 – 28 days later to complete the vaccination series.

If you have any further questions on the use of Covid-19 Vaccine LHC, ask your doctor, pharmacist or nurse.

### **4. Possible side effects**

*Very common*

Pain at the injection site

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### *Common*

Transient fever, fatigue, headache, diarrhoea; redness, swelling, itching, and hardening at the injection site

### *Uncommon*

Skin rash at the injection site; nausea and vomiting, itching at the non-injection site, muscle pain, arthralgia, drowsiness, dizziness.

### *Serious adverse reaction*

So far, no vaccine-related serious adverse reaction was observed

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Covid-19 Vaccine LHC.

## **5. How to store Covid-19 Vaccine LHC**

Do not use after the expiry date on the pack.

Store in a refrigerator between 2 and 8 °C

Protect from light

Do not freeze.

## **6. Contents of the pack and other information**

### **What Covid-19 Vaccine LHC contains**

The active substance is Inactivated SARS-CoV-2 antigen cultured in Vero Cell.

The other ingredients are Sodium Chloride, Disodium Hydrogen Phosphate, Sodium Dihydrogen Phosphate and Aluminium Hydroxide.

### **What Covid-19 Vaccine LHC looks like and contents of the pack**

The product is semi-transparent suspension which displays a slightly white to off-white

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colour after shaking, could be layered by precipitation, and the precipitation can be easily dispersed by shaking.

The pack contains either one pre-filled syringe or one 2 ml vial.

Each syringe or vial contains one 0.5 ml dose of vaccine.

The pre-filled syringe (1 ml) is composed of the needle cover, needle-bearing glass tube, plunger rubber cap and plunger stick.

The vial (2 ml) is composed of film-coated middle-borosilicate glass vials, aluminium foil cap and film-coated rubber stopper.

### **Holder of Certificate of Registration**

LHC PHARMACEUTICALS (PTY) LTD

N4 Gateway Industrial Park

553 Willow Park Manor, 33 Ghaap Street

Pretoria, 0184

### **This leaflet was last revised in**

### **Registration number**

To be allocated