PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

Covid-19 Vaccine LHC

4 µg/0.5 ml dose

Suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml contains one dose, 4 µg of Inactivated SARS-CoV-2 antigen cultured in Vero Cell.

Adjuvant: Aluminium hydroxide 0.225 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.

A semi-transparent suspension which displays a slightly white to off-white colour after shaking and could be layered by precipitation, and the precipitation can be easily dispersed by shaking.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age and older.

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4.2 Posology and method of administration

Posology: Individuals 18 years of age and older

Two doses are administered by a healthcare professional into the deltoid muscle at an interval of 21-28 days, each dose is 0.5 mL and contains 4 µg/dose

Paediatric population

The safety and efficacy of Covid-19 Vaccine LHC in children have not yet been established.

Method of Administration: The Covid-19 Vaccine LHC is administered intramuscularly into the deltoid muscle.

The vaccine should be thoroughly shaken before use.

Do not allow disinfectant to come into contact with the vaccine when the protective cap is removed.

The vaccine should be used immediately after opening.

Do not use if any abnormalities are observed such as visible particles, damaged label, beyond expiry date or cracks in the syringe or vial are present.

4.3 Contraindications

(1) Individuals who are hypersensitive to any component (active or excipients) of this product, or those who have had 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.

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4.4 Special warnings and precautions for use

Intravenous injection is strictly prohibited.

The effect of freeze thaw cycles has not been established. Do not use the vaccine if it has been frozen as its antigenicity will have been compromised.

Medicines and equipment should be available for emergency treatment in the event of an occasional severe allergic reaction.

The vaccinee should be watched for at least 30 minutes after vaccination.

This vaccine should be used with caution in the following circumstances:

(1) Individuals who 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) Individuals who are taking immunosuppressants, in such cases it is recommended to postpone vaccination until the end of the treatment to make sure the subject is well protected.
(3) Individuals who have chronic immune deficiency, may be vaccinated even though the underlying disease may cause a limited immune response.
(4) Uncontrolled epilepsy and other progressive neurological disorders.

Like all vaccines, this product may not have 100% preventive effect for the vaccinee.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

Concomitant administration with other vaccines has not been studied.

Do not mix Covid-19 Vaccine LHC with other vaccines/products in the same syringe.

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4.6 Fertility, pregnancy and lactation

Pregnancy

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

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). Administration of the Covid-19 Vaccine LHC in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Breast-feeding

It is unknown whether the Covid-19 Vaccine LHC is excreted in human milk.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3)

4.7 Effects on ability to drive and use 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 4.8 may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Systemic adverse reactions are mainly fever and diarrhoea, and local adverse reactions are mainly pain followed by swelling.

All the adverse events occurred within 7 days of vaccination.

The occurrence rate for ADRs can be presented as:

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Very common (≥ 1/10),

Common (≥ 1/100 to < 1/10),

Uncommon (≥ 1/1,000 to < 1/100),

Rare (≥ 1/10,000 to < 1/1,000),

Very rare (< 1/10,000),

(1) Very common: Pain at the injection site;

(2) Common: Transient fever, fatigue, headache, diarrhoea; 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.

(4) No vaccine-related serious adverse reaction have been observed.

MeDRA System Organ Class	**Frequency**	**Undesirable Effects**
Immune system disorders	Uncommon	Itching not at the injection site
Nervous system disorders	Common	fatigue, headache
	Uncommon	drowsiness, dizziness
Gastrointestinal disorders	common	diarrhoea
	Uncommon	Nausea and vomiting

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Musculoskeletal and connective tissue disorders	Uncommon	Arthralgia; Myalgia
General disorders and administration site conditions	Very common	pain at injection site
	Common	redness, swelling, itching, and hardening at injection site. Transient fever, fatigue, headache.
	Uncommon	Skin rash at the injection site

Participants were monitored after each vaccination for 30 minutes for immediate reactions.

Solicited injection site and systemic reactions were recorded in a diary card for 7 consecutive days after each vaccination. Participants were monitored for 28 days for unsolicited adverse events and for 12 months post-vaccination for visits to an emergency room, unexpected visits to an office physician, and serious adverse events. Unsolicited adverse event information was obtained either by telephone interview or at an interim clinic visit.

The most frequently reported solicited injection site and systemic reactions within 7 days following vaccination in adults aged 18 years and elder were injection site pain. Fever, fatigue, headache, and diarrhoea were also common**.**

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Paediatric population

The clinical trials to evaluate the safety and immunogenicity in population aged between 3 years and 17 years old are ongoing.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Mechanism of Action: Inactivated SARS-CoV-2 Antigen cultured in Vero Cell elicits a neutralising antibody response in the vaccinee which may contribute to protection against Covid-19 disease.

Immunogenicity was evaluated in a randomized, double-blind, placebo-controlled, phase 1/11 trials that enrolled children (3 through 12 years of age), adolescents (13 through 17 years of age), and adults (18 through 59 years of age, and >60 years of age) in China,

assessed as the neutralizing antibody responses against infectious SARS-CoV-2. Humoral responses against SARS-CoV-2 were induced in all vaccine recipients on day 14 after the second dose. Two-dose schedule with 4 micrograms vaccine on days 0 and 21 achieved higher neutralizing antibody titres in population aged 18 years and above.

The clinical trial results showed that the COVID-19 Vaccine (Vero Cell), Inactivated has good safety in all age groups and dosage groups.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Animal studies do not indicate any potential direct or indirect harmful effects to humans with respect to standard toxicity testing in rats or in Macaca Fascicularis

Reproductive and developmental toxicity were investigated in SD rats in a combined fertility and developmental toxicity study. There were no vaccine-related effects on female fertility, pregnancy, or embryo-foetal or offspring development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride

Disodium Hydrogen Phosphate

Sodium Dihydrogen Phosphate

Aluminium Hydroxide

6.2 Incompatibilities

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Concomitant administration with other vaccines has not been studied.

Do not mix Covid-19 Vaccine LHC with other vaccines/products in the same syringe.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store between 2 and 8 °C

Protect from light. Do not freeze

6.5 Nature and contents of container

The product is semi-transparent suspension which displays a slightly white to off-white colour after shaking, could be layered by precipitation, and the precipitation can be easily dispersed by shaking.

The container is either a 1 ml pre-filled syringe or a 2 ml vial.

Each syringe or vial contains a single 0.5 ml dose.

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.

Pack size:

1 syringe/box

1 vial/box or 3 vials/box.

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Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

Discard any unused vaccine.

Any unused vaccine must be discarded at the end of the vaccination session.

Needles used for Coronavirus vaccinations are considered sharps waste and therefore must be disposed of in Biohazard bins.

All vaccines must be destroyed at a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008) and such destruction must be certified.

7 HOLDER OF CERTIFICATE OF REGISTRATION

LHC PHARMACEUTICALS (PTY) LTD

N4 Gateway Industrial Park

553 Willow Park Manor, 33 Ghaap Street

Pretoria, 0184

8 REGISTRATION NUMBER(S)

To be included once Registration Certificate is received.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10th May 2022.

10 DATE OF REVISION OF THE TEXT