Stamp: MINISTRY OF HEALTH OF RUSSIA * LP-007967-180322 * APPROVED

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

INSTRUCTIONS FOR MEDICAL USE OF PHARMACEUTICAL PRODUCT

Convacell®

Subunit recombinant vaccine for the prevention of coronavirus infection caused by the SARS-CoV-2 virus

▼ This pharmaceutical product is registered in accordance with the registration procedure for products intended for use in case of a threat, occurrence and liquidation of emergency situations. The instruction is prepared according to limited clinical data on the use of the pharmaceutical product and will be supplemented as new data becomes available. This product may be used only in medical facilities authorized to carry out vaccinations in the prescribed manner.

Registration number:

Trade name: Convacell®, subunit recombinant vaccine for the prevention of coronavirus infection caused by the SARS-CoV-2 virus.

International non-proprietary or generic name: COVID-19 vaccine.

Pharmaceutical form: emulsion for intramuscular injection.

Composition

1 dose (0.5 mL) contains:

Active substance:

Recombinant N protein of the SARS-CoV-2 virus - 50.0 μg

Excipients:

Squalane - 15 mg, (D, L)-α-tocopherol - 5 mg, polysorbate 80-5 mg, disodium hydrogen phosphate dodecahydrate - 1.79 mg, potassium dihydrogen phosphate - 0.12 mg, potassium chloride - 0.10 mg , sodium chloride - 4.00 mg, water for injections - up to 0.5 ml.

Description

White or yellowish liquid, stratification that disappears after shaking is allowed.

Characteristic

Convacell® is a recombinant nucleocapsid protein of the SARS-CoV-2 virus obtained in *Escherichia coli* and a mixture of excipients (squalane, (D,L)-α-tocopherol, polysorbate 80) in the form of emulsion.

Pharmacotherapeutic group

Immunological pharmaceutical product, vaccine.

ATC code: J07B.

Pharmacological properties

Mode of Action

Vaccination with Convacell® generates humoral and cellular immunity that prevents the development of coronavirus infection caused by the SARS-CoV-2 virus. On the surface of droplets of excipients emulsion, N protein is presented to monocytes attracted from the blood flow due to a local increase in the level of cytokines. Antigen-bearing cells migrate to draining lymph nodes with activation of innate and adaptive immune cells. The activation of natural killers in combination with specific antibodies triggers the mechanism of lysis of infected cells. The nucleocapsid protein (N) is conservative and slightly susceptible to mutational changes. This makes the vaccine versatile for different coronavirus strains.

Immunogenicity

Clinical trials on volunteers have shown the safety immunogenicity of the vaccine. All volunteers showed the production and growth of IgG antibodies to the N protein, as well as the activation of a specific cellular immune response. In volunteers the geometric mean IgG titer increased from 0.162 at

baseline to 3.556 on Day 21 after vaccination and to 8.158 on Day 42 after vaccination, while the increase in the geometric mean titer on Days 21 and 42 was 21.9 and 50.4, respectively. On Days 21 and 42 after primary vaccination, the proportion of seropositive (IgG) volunteers was 79.55 and 100.00%, respectively, and the seroconversion rate reached 79.55 and 100.00%, respectively. The analysis of the antigen-specific cellular immune response showed a significant increase in IFN-y and IL-2 producing helpers in volunteers treated with the vaccine as compared to volunteers from the "Placebo" group on Day 42 of the follow-up ($r<0.05$).

The duration of post-vaccination immunity and protection is being studied.

Indications

Prevention of the new coronavirus infection (COVID-19) in adults aged 18 to 60 years.

Contraindications

Hypersensitivity to any component of the vaccine or a vaccine containing similar components.

History of severe allergic reactions.

Allergic or post-vaccination complications after previous vaccinations.

Acute infectious and non-infectious diseases, exacerbation of chronic diseases – the vaccination should be carried out 2-4 weeks after recovery or during remission. In case of non-severe acute upper respiratory infections or acute intestinal infectious diseases – vaccination is performed after the body temperature has returned to normal.

Pregnancy and breastfeeding.

Age under 18 years (due to the lack of efficacy and safety data).

Age over 60 years (due to the lack of efficacy and safety data).

Use with caution

Use the vaccine with caution in case of chronic liver and kidney diseases, endocrine diseases (severe decompensated thyroid dysfunction and diabetes mellitus), severe diseases of the hematopoietic system, epilepsy and other diseases of the central nervous system, acute coronary syndrome and acute cerebrovascular accident, myocarditis, endocarditis, pericarditis, primary and secondary immunodeficiencies, autoimmune diseases, allergic reactions.

Due to the lack of information, the vaccination can pose a risk for the following patient groups:

- suffering from autoimmune diseases (stimulation of the immune system can lead to an exacerbation, especially in patients with autoimmune disorders, which tends to develop severe and life-threatening conditions, should be treated with caution);
- with malignant neoplasms.

The decision to vaccinate should be based on an assessment of the risk to benefit ratio on a case by case basis.

Use during pregnancy and lactation

The product is contraindicated during pregnancy and breastfeeding, since its efficiency and safety in these physiological conditions have not been studied.

Method of administration and doses.

The vaccine is administered **twice with an interval of 21 days** at a dose of 0.5 mL, intramuscularly, in the upper third of the outer surface of the shoulder (in the region of the deltoid muscle).

Before use, keep the ampoule with the vaccine until it reaches the room temperature, carefully mix the contents by rotating, gentle inversion is allowable. If the emulsion is separated, continue mixing it until the contents become homogenous (white or yellowing liquid).

Open the ampoules and carry out the vaccination in strict compliance with aseptic and antiseptic rules: before opening, wipe the neck of the ampoule with a sterile cloth soaked with 70% ethyl alcohol, open the ampoule, fill a disposable syringe with the vaccine and remove excess air from the syringe. Wipe the skin at the injection site with 70% ethyl alcohol.

Do not store the product after opening the ampoule!

Information for healthcare workers performing vaccination: this pharmaceutical product is registered

according to a special marketing authorization procedure and therefore it is necessary to notify the Federal Service for Surveillance in Healthcare about each fact of using the pharmaceutical product by entering information in the appropriate section of the USHIS information system.

Side effects.

The incidence of side reactions is reported in accordance with the WHO classification of ADRs based on findings from completed clinical trials.

The incidence is determined according to the following criteria: very common (≥ 1/10), common (≥ 1/100 and <1/10), uncommon (≥ 1/1,000 and <1/100), rare (≥ 1/10,000 and <1/1,000), very rare (<1/10,000, including sporadic cases).

Table 1. Adverse reactions observed in clinical trials in persons aged 18-60 years.

Adverse reactions according to the classes of organ systems according to medical dictionary for MedDRA regulatory activities	**Incidence**
Infections and invasions	
Flu-like syndrome	Uncommon
Nervous system disorders	
Headache	Common
Eye disorders	
Eye dryness	Common
Hearing and labyrinth disorders	
Ear pain	Common
Respiratory, thoracic and mediastinal disorders	
Throat irritation	Common
Gastrointestinal disorders	
Vomiting	Common
Skin and subcutaneous tissue disorders	
Increased sweating	Common
Musculoskeletal, muscle and connective tissue disorders	
Muscle pain	Common
Joint pain	Common
General disorders and administration site conditions	
Pain in the site of vaccination	Very common
Vaccination site induration	Very common
Pruritus in the site of vaccination	Common
Edema at the injection site	Common
Erythema at the injection site	Common
Chills	Common
Malaise	Common
Fatigue	Common
Fever	Common
Feeling of change in body temperature	Common
Hyperthermia	Common

The patient should be informed of the need to report the doctor about any pronounced side effects or events not specified in this instruction.

Overdose

No cases of overdose have been reported.

Taking into account that the vaccine may be released to medical institutions only and the

vaccination is carried out by qualified medical personnel, the risk of overdose is extremely low. However, it can be assumed that in case of accidental overdose, the development of allergic reactions is possible. There are no specific antidotes for this pharmaceutical product. Therapeutic measures in this case will include symptomatic therapy in accordance with indications.

Interaction with other pharmaceutical products

No special trials of interaction with other medicinal products have been conducted.

Convacell® should not be mixed with other vaccines or medicinal products in the same syringe, as there is no data on pharmaceutical interactions.

Special indications

The vaccine is intended for intramuscular injection only. Not for intravenous injection!

The pharmaceutical product is not suitable for use if the ampoule or its label is damaged, if emulsion shows changed physical properties (color) or contains foreign particles, after the expiry date or if stored and/or transported under inappropriate conditions.

Before the vaccination, the patients must be examined by a doctor (paramedic) and have body temperature measured. The vaccination is not allowed if the body temperature exceeds 37 °C.

Anti-shock means must be available in the rooms used for vaccination according to Order of the Ministry of Health of the Russian Federation No. 1079 dated December 20, 2012 “On Approval of the Standard for Emergency Medical Care for Anaphylactic Shock”. The vaccinee should be observed by a health worker for 30 minutes after vaccination.

Unused ampoules should be disposed of according to the applicable law.

The vaccination of patients receiving immunosuppressive therapy (corticosteroids, cytotoxic products, radiotherapy) may be less effective.

Like with other vaccines, not all vaccinated individuals may develop a protective immune response.

When a doctor (medical worker) makes a decision on the need to simultaneously administer Convacell® and another vaccine, they should not be mixed in the same syringe and injected into the same part of the body.

Effect on the ability to drive vehicles, machinery:

Trials on the effect of Convacell® on the ability to drive vehicles and operate potentially dangerous machinery have not been conducted.

Pack form

Emulsion for intramuscular injection, 0.5 mL/dose.

0.5 mL (1 dose) of the emulsion in clear glass ampoules.

Ten ampoules in each pack of packaging cardboard with inner dividers.

One blister pack in a cardboard box for consumer package, with instruction for use.

Storage conditions

In a place protected from light at a temperature of 2 to 8 °C. Do not freeze.

Keep away from the reach of children.

Transportation conditions

Transport at a temperature of 2 to 8 °C. Do not freeze.

Shelf life

6 months. Do not use after shelf life expiry.

Prescription status

For medical facilities.

Manufacturer

Federal State Unitary Enterprise “Saint Petersburg Scientific Research Institute of Vaccines and Sera and Enterprise for the Production of Bacterial Preparations” of the Federal Medical and Biologic Agency (FSUE SPbSRIVS FMBA of Russia)

Manufacturing of finished pharmaceutical form

Russia, 198320, Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, Letter B.

Primary packaging

Russia, 198320, Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, Letter B.

Secondary (consumer) packaging

Russia, 198320, Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, Letter B.

Russia, 198320, Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, Letter D.

Release quality control

Russia, 198320, Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, Letter A Tel.: +7 (812) 660-06-14; fax: +7 (812) 660-06-16.

Marketing Authorization holder/organization receiving consumer complaints.

FSUE SPbSRIVS FMBA of Russia. Russia.

198320, Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, tel.: +7 (812) 660- 06-10, +7(812) 660-06-11.

Any complaints about the quality of the pharmaceutical product or information on cases of increased reactogenicity or development of post-vaccination complications should be sent to the body corporate in whose name the marketing authorization is issued (Russia, 198320, Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, tel.: +7 (812) 660-06-10, +7 (812) 660-06-11, +7 (812) 741-19-00, +7 (812) 741-19-78; http://spbniivs.ru; vigilance@spbniivs.ru) indicating the batch number and manufacture date (last four digits of the batch number) of the pharmaceutical product, followed by the submission of medical documentation.

Director *Stamp*: THE DOCUMENT IS SIGNED WITH ELECTRONIC SIGNATURE * Certificate: 029DCF8A0034AD59814FCC904C5CA08608 * Holder: Viktor Pavlovich Trukhin * Valid: from May 26, 2021 to August 26, 2022 V.P. Trukhin