/Coat of Arms of the Russian Federation/
MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

Marketing Authorization of pharmaceutical product for human use

LP-007967

(number of marketing authorization for pharmaceutical product)

Name of the holder of Marketing Authorization for pharmaceutical product	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). Russia
Address of the holder of Marketing Authorization for pharmaceutical product	198320, Saint Petersburg, Krasnoe Selo, ul. Svobody, 52
Date of state registration of pharmaceutical product	**March 18, 2022**
Period of validity of the Marketing Authorization for pharmaceutical product	January 01, 2023
Date of amendment of the Marketing Authorization for pharmaceutical product (date of replacement of the Marketing Authorization for the pharmaceutical product)	
Information about the registered pharmaceutical product:	
Trade name	Convacell® Subunit recombinant vaccine for the prevention of coronavirus infection caused by the SARS-CoV-2 virus
International non-proprietary, generic or chemical name	COVID-19 vaccine
Pharmaceutical form	emulsion for intramuscular injection
Dosage	0.5 mL/dose
Qualitative and quantitative composition of active ingredients and qualitative composition of excipients	
recombinant N protein of the SARS-CoV-2 virus 50.0 μg, excipients (squalane, polysorbate 80, (D,L)-α-tocopherol, disodium hydrogen phosphate dodecahydrate, potassium dihydrogen phosphate, potassium chloride, sodium chloride, water for injections)	
Pack form (pharmaceutical form, dosage, primary, amount of dosage form in primary packaging, amount of primary packaging in the consumer package, completeness)	emulsion for intramuscular injection, 0.5 mL/dose (ampoule) 0.5 mL (1 dose) x 10 (cardboard box)
Details of regulatory documents	LP-007967-180322

Production sites participating in the process of manufacturing of pharmaceutical product with the indication of production stages, names and actual location addresses	
Manufacture of finished pharmaceutical form	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), Russia
Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, letter B	
Primary packaging	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), Russia
Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, letter B	
Secondary/consumer packaging	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), Russia
Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, letter B, D	
Manufacturer (Release quality control)	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), Russia
Saint Petersburg, Krasnoe Selo, ul. Svobody, 52, letter A	

Special conditions for registration of the pharmaceutical product	
1.	This pharmaceutical product for human use can be used in healthcare facilities only, which are entitled to carry out human vaccinations in the manner prescribed by law.
2.	Compulsory quality testing of each batch (lot) of the pharmaceutical products for compliance with the registration dossier by federal state budget institutions accredited in the national accreditation system in accordance with the Russian law that report to the Ministry of Health of the Russian Federation and the Federal Service for Surveillance in Healthcare, with submission of the required quantity of pharmaceutical products, reference standards, reagents and materials to the institutions and reporting the test results to the Federal Service for Surveillance in Healthcare;
3.	Submission of the final report on the clinical trial for assessing the immunogenicity, safety and tolerability of the vaccine.

4.	Entering information into the Unified State Health Information System about each fact of using the pharmaceutical product.
5.	Reporting to the Federal Service for Surveillance in Healthcare about any side effects, adverse reactions, serious and unexpected adverse reactions to the use of the pharmaceutical product, about its interaction with other pharmaceutical products, individual tolerability, as well as other facts and circumstances that pose a threat to life or health or affect the benefit to risk ratio of the pharmaceutical products and were detected at any stage of use.

Deputy Minister *_____/Signature/_____* **A.N. Plutnitsky**

(signature)

Seal: Ministry of Health of the Russian Federation * (Minzdrav of Russia)

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