

FACT SHEET FOR VACCINE RECIPIENTS AND CAREGIVERS
APPROVED FOR RESTRICTED USE IN EMERGENCY SITUATION IN PUBLIC INTEREST

THE DR. REDDY'S LABORATORIES COVID-19 VACCINE (SPUTNIK V™) GAM-COVID-VAC COMBINED VECTOR VACCINE FOR THE PREVENTION OF CORONAVIRUS INFECTION CAUSED BY THE SARS-COV-2 VIRUS IN INDIVIDUALS ABOVE 18 YEARS

This vaccine has been given restricted use license for emergency situation. It does not have a marketing authorization, however, this approval for the restricted use in emergency situation grants permission for the vaccine to be used for active immunization of individuals above 18 years for the prevention of coronavirus disease 2019 (COVID-19).

Reporting of side effects

As with any new medicine, this vaccine will be closely monitored to allow quick identification of new safety information. You can help by reporting any side effects you may get after vaccination to the Dr. Reddy's Laboratories Ltd., on 24x7 Toll-Free Number: +91-1800 425 0014 or at customerservices@drreddys.com. All adverse events reported will be entered in COWIN App by the health care provider. For more information read this fact sheet carefully.

You are being offered the Dr. Reddy's Laboratories Ltd. (DRL) SPUTNIK V Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the SPUTNIK V Vaccine, which you may receive because there is currently a pandemic of COVID-19 disease.

The SPUTNIK V is a vaccine and may prevent you from getting COVID-19 disease.

Please read this Fact Sheet for information about the Dr Reddys laboratories COVID-19 Vaccine (SUTNIK V). Talk to Vaccinator/ Officer supervising your vaccination if you have any questions.

It is your choice to receive the Dr Reddys laboratories COVID-19 Vaccine (SPUTNIK V).

The Dr Reddys laboratories COVID-19 Vaccine (SPUTNIK V) is carried out in two stages: first with component I, then 3 weeks later with component II. The product is administered intramuscularly: first component I at a dose of 0.5 ml, then after 3 weeks component II at a dose of 0.5 ml.

After the vaccine is administered, the patient should be monitored by a healthcare professional for 30 minutes.

The SPUTNIK V may not protect everyone.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE SPUTNIK V VACCINE?

Sputnik V is Gam-COVID-Vac Combined vector vaccine for the prevention of coronavirus infection caused by the SARS-CoV-2 virus in individuals over 18 years.

WHAT YOU NEED TO KNOW BEFORE YOU USE SPUTNIK V

Tell your healthcare provider about all of your medical conditions, including:

- If you have kidney or liver problems, severe disorders of the endocrine system (diabetes mellitus), severe diseases of the hematopoietic system, epilepsy, strokes and other diseases of the central nervous system,
- If you have diseases of the cardiovascular system (history of myocardial infarction, myocarditis, endocarditis, pericarditis, ischemic heart disease),
- If you have primary and secondary immunodeficiency, autoimmune diseases,
- If you have lung diseases, asthma and COPD, with allergic reactions, atopy, eczema
- If you are pregnant or plan to become pregnant
- If you are breastfeeding or plan to breastfeed
- If you have any other serious illnesses
- If you are taking any medicines (prescription, over-the-counter, vitamins, or herbal products).

You should consult your healthcare provider before deciding to take the vaccine.

WHO SHOULD GET THE SPUTNIK V VACCINE?

SPUTNIK V Vaccine has been approved for restricted use in emergency situation in individuals over 18 years.

WHO SHOULD NOT GET THE SPUTNIK V Vaccine?

If you have

- hypersensitivity to any component of a vaccine or a vaccine containing similar components
- history of severe allergic reactions
- if you are suffering from common cold, runny nose, fever, cough, bodyache or loose motions etc
- pregnancy and the period of lactation
- age up to 18 years (due to lack of data on efficacy and safety)
- developed severe post-vaccination complications (anaphylactic shock, severe generalized allergic reactions, convulsive syndrome, temperature above 40°C, etc.) for the injection of component I of the vaccine

WHAT ARE THE INGREDIENTS IN THE SPUTNIK V VACCINE?

Component I contains:

Active substance: Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene $1.0 \pm 0.5 \times 10^{11}$ Particles.

Excipients: Tris (hydroxymethyl) aminomethane -1.21 mg, sodium chloride - 2.19 mg, sucrose -25.0 mg, magnesium chloride hexahydrate -102.0 µg, EDTA disodium salt dehydrate - 19.0 µg, polysorbate 80 - 250.0 µg, ethanol 95% - 2.50 µl, water for injection Q.s to 0.5 ml.

Component II contains:

Active ingredient: Recombinant adenovirus serotype 5 particles containing the SARS-CoV-2 protein S gene $1.0 \pm 0.5 \times 10^{11}$ Particles.

Excipients: Tris (hydroxymethyl) aminomethane -1.21 mg, sodium chloride - 2.19 mg, sucrose -25.0 mg, magnesium chloride hexahydrate -102.0 µg, EDTA disodium salt dehydrate - 19.0 µg, polysorbate 80 - 250.0 µg, ethanol 95% - 2.50 µl, water for injection Q.s to 0.5 ml.

HOW IS THE SPUTNIK V GIVEN?

The SPUTNIK V Vaccine will be given to you as an intramuscular (IM) injection only, preferably in the deltoid muscle.

The SPUTNIK V vaccination course consists of two separate doses of 0.5 ml each.

If you receive first dose of the sputnik v vaccine, then the second dose should be administered after 3 weeks with second dose.

After the vaccine is administered, you will be monitored by a healthcare professional for 30 minutes.

If you miss your second dose

If you forget to go back at the scheduled time, ask your healthcare provider for advice.

HAS THE SPUTNIK V VACCINE BEEN USED BEFORE?

The SPUTNIK V is used in clinical trials, a number of participants received one or two doses in overseas and Indian trials.

WHAT ARE THE BENEFITS OF THE SPUTNIK V VACCINE?

In ongoing clinical trials, the SPUTNIK V Vaccine has been shown to prevent COVID-19 disease following 2 doses given at 3 weeks interval i.e. days 1 and 21. The duration of protection against COVID-19 disease is currently unknown.

You may get protective immune response within 1 to 3 weeks after the second dose of SPUTNIK V vaccine. Hence, you must practice the COVID-19 precautions recommended to prevent SARS-COV-2 infection till 3 weeks after the second dose of the vaccine i.e. day 42 from the first dose of vaccine.

WHAT ARE THE RISKS OF THE SPUTNIK V VACCINE?

Side effects that have been reported with the SPUTNIKV Vaccine include:

Very common (may affect more than 1 in 10 people)

- Tenderness, pain, warmth, redness, itching, swelling or bruising where the injection is given
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

Common (may affect 1 in 10 people)

- Headache
- Feeling tired
- Feeling feverish or chills
- Muscle pain
- Runny nose
- Cough

Uncommon (may affect upto 1 in 100people)

- Feeling sick(Nausea)
- Being sick(Vomiting)
- Stomach ache
- Joint pain,
- Decrease appetite
- Sore throat
- Nasal congestion
- Impaired sense of taste
- Doubtfulness

These may not be all the possible side effects of the SPUTNIK V Vaccine.

Serious and unexpected side effects may occur. **SPUTNIK V Vaccine is still being studied in clinical trials and follow up on the trials is going on.**

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call or go to the nearest hospital.

Call the healthcare provider if you have any side effects that bother you or do not go away.

In addition, you can report side effects after vaccination to Dr.REDDY'S LABORATORIES Ltd. as below.

- 24x7 Call Center Toll-Free Number (For Medical and Adverse Event Related Queries Only): Toll-Free Number: +91-1800 425 0014 or at customerservices@drreddys.com.

All adverse events reported will be entered in COWIN App by the health care provider.

WHAT IF I DECIDE NOT TO GET THE SPUTNIK V VACCINE?

It is your choice to receive or not receive the SPUTNIK V Vaccine. You may prefer to consult your healthcare provider.

CAN I RECEIVE THE SPUTNIK V VACCINE WITH OTHER VACCINES?

There is no information on the use of the **SPUTNIK V Vaccine** with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

You may discuss your options with the healthcare provider.

WILL THE SPUTNIK V VACCINE GIVE ME COVID-19 INFECTION?

No. The **SPUTNIK V** COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19 infection.

KEEP YOUR VACCINATION CARD

When you get your dose, please discuss with your healthcare provider regarding the option of your vaccination record on digital platform, if available.

HOW CAN I LEARN MORE?

- Ask the healthcare provider.
- Contact your local or state public health department.

DETAILS OF MANUFACTURER

The Gamaleya National Center of Epidemiology and Microbiology of the Ministry of Health of the Russian Federation

At: GENERIUM Joint-Stock Company (GENERIUM JSC), 273 Zavodskaya Street, Volginsky, Petushinsky District, Vladimir Region, 601125 (Russia)

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