Sputnik V ™

Gam-COVID-Vac

Combined vector vaccine for the prevention of coronavirus infection caused by the SARS-CoV-2 virus

1. GENERIC NAME

Gam-COVID-Vac Combined vector vaccine **(Component I) - 0.5 ml/dose & (Component II) - 0.5 ml/dose**

Trade Name: Component I - Gam-COVID-Vac Combined vector vaccine (Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene, in an amount of (1.0 ± 0.5) x 10^{11} particles / dose) to prevent SARS-CoV- 2-induced coronavirus infection.

Component II - Gam-COVID-Vac Combined vector vaccine (Recombinant adenovirus serotype 5 particles containing the SARS-CoV-2 protein S gene, in an amount of (1.0 ± 0.5) x 10^{11} particles / dose) to prevent SARS-CoV-2-induced coronavirus infection.

International nonproprietary, generic, or chemical name: Vaccine to help prevent the newly discovered coronavirus infection (COVID-19).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per dose (0.5 ml):

Component I contains:

Active substance: Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene 1.0±0.5 x 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 substance: Recombinant adenovirus serotype 5 particles containing the SARS-CoV-2 protein S gene 1.0±0.5 x 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.

3. DOSAGE FORM AND STRENGTH

A solution for intramuscular injection. Component I - 0.5 ml / dose + component II - 0.5 ml / dose

4. CLINICAL PARTICULARS

4.1 Indications:

For the prevention of the novel Coronavirus infection (COVID-19) in adults aged over 18, when given in two separate doses three weeks apart.

Day 0: Component I (0.5 ml) & Day 21: Component II (0.5 ml)

4.2 Posology and Administration:

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

The vaccination 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.

Special populations

Elderly population

Efficacy was similar in elderly population of more than 60 years of age as compared to adults less than 60 years of age.

Paediatric population

The safety and efficacy of SPUTNIK V in children and adolescents (aged <18 years old) have not yet been established. No data are available.

Method of administration:

The vaccine is intended for intramuscular injection only. Intravenous injection of the product is strictly prohibited. The vaccine is injected into the deltoid muscle (the upper third of the outer shoulder). If it is impossible to inject into the deltoid muscle, the product is injected into the vastus lateralis muscle.

For instructions on administration

Prior to vaccination with either Component I or Component II, take a ampoule of the intended component out of the freezer and keep at room temperature (15-25°C) until completely thawed with no visible frozen inclusions. The ampoule may be held in hands to help it thaw.

Carefully mix the contents of the ampoule by swirling gently in an upright position for 10 seconds. Do not shake the ampoule.

With a single-use syringe, draw 0.5 mL of the drug as a dose to administer to the patient.

After being thawed, the vaccine may be stored at room temperature (15-25° C) for up to 2 hours. Unused contents after this period must be discarded.

4.3 Contraindications:

Contraindications for the injection of component I

- Hypersensitivity to any constituents of the vaccine.
- Severe allergic reactions in the past;
- Pregnant women.
- Individuals below 18 years.
- Acute infectious and non-infectious diseases, exacerbation of chronic diseases - vaccination is carried out 2-4 weeks after recovery or remission. In case of nonserious ARVI, acute gastrointestinal infections vaccination is carried out after the temperature has returned to normal;

Contraindications for the injection of component II

- 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;

4.4 Use with Caution

The vaccine should be used with caution in cases of chronic liver and kidney disease, endocrine disorders (apparent thyroid function abnormalities and diabetes mellitus in decompensation stage), serious diseases of the hematopoietic system, epilepsy and other CNS diseases, acute coronary syndrome, and acute cerebrovascular event, myocarditis, endocarditis, pericarditis.

Due to lack of data, vaccination may be a risk for the following groups of patients:

- With autoimmune diseases (stimulation of the immune system can lead to an exacerbation of the disease, special caution should be exercised with patients with an autoimmune disorder that tend to lead to severe and life-threatening conditions);
- With malignant neoplasms.

The decision to vaccinate should be based on the assessment of the benefit/risk ratio in each specific situation.

4.5 Drug Interactions

No interaction studies have been performed.

Concomitant administration of SPUTNIK V with other vaccines has not been studied.

4.6. Use in Special Populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

It is not anticipated that there is a biologically plausible way in which the vaccine could cause infertility in any woman or man, developmental pathology, or affect offspring, since:

- The vaccine does not use adjuvants;
- The potentially toxic (in rats) excipient (polysorbate 80) used in the vaccine is used in a dose that cannot affect human fertility or the reproductive function
- The vaccine virus does not reproduce itself; after injection, the virus delivers the S protein gene to the cell and ceases to exist in the human body – The gene coding S protein in the body leads to the production of the viral S protein, and the development of an immune response to it
- Antibodies to the S protein produced in response to immunization are similar to the antibodies produced in response to a disease caused by SARS-CoV-2, therefore, the risk associated with immunization is not higher than that for infection
- Antibodies to adenovirus produced in response to immunization are similar to antibodies to adenoviruses produced in response to a disease caused by adenovirus with a widely spread pathogen; therefore, the risk associated immunization is not higher than that for infection.
- In preclinical studies of reproductive toxicity, a similar vaccine developed based on adenovirus vectors types 26 and 5 of identical composition was studied. No increased risk is expected with administering the drug in active reproductive populations given adherence to the restrictions indicated in the instructions for medical use.

Using during pregnancy and breastfeeding

The drug is contraindicated during pregnancy, since its efficacy and safety in these conditions have not been studied.

Gam- COVID- Vac can be administered safely in lactating women.

Pediatric Use

There were no studies done on children. No children vaccination is stipulated at this development stage.

Use in Elderly Subjects

There were no studies done on elderly subjects. Based on the safety profile studied as part of the clinical study entitled Open Study of Safety, Tolerability, and Immunogenicity of the Gam-COVID-Vac Drug, Solution for Intramuscular Injections, in Healthy Volunteers, the solution for intramuscular injections does not differ from any other similar drugs, no SAE (Serious adverse events) are detected, and adverse events detected are typical for vaccines in general.

Specific Instructions

Patients undergoing immunosuppressive therapy and immunosuppressed patients may not develop a sufficient immune response. Therefore, any drugs that suppress the immune system's function are contraindicated at least within 1 month before and after vaccination due to the risk of immunogenicity reduction.

4.7. Effects on Ability to Drive and Use Machines

There is no information regarding the effects on ability to drive and use machines.

4.8. Undesirable Effects

Phase III Clinical Trial in Russia (RESIST, NCT04530396)

A safety analysis in Phase III Study conducted in Russia included **33,771** volunteers (all volunteers who were administered a dose of the study drug), which included 2990 volunteers > 60 years of age. Volunteers aged 18 to 92 years were included in the study. The average age was 43.9 ± 12.1 years in group I (SD) and 43.9 ± 12.0 years in group II (Placebo). 22,419 male volunteers (16,771 – in the SD group and 5,648 in the placebo group) and 11,347 female volunteers (8,545 – in the SD group and 2,799 – in the placebo group). Large majority of volunteers were Caucasians (about 97%), 1,023 volunteers were Asian, and 130 volunteers belonged to other races.

In the study, 26,405 cases of AE have been reported to date, developed in 12,080 volunteers (35.8%). The AEs reported in association with vaccination were observed in 9,323volunteers (36.8%). Of these, the commonly reported (>3%) were flu like illness (20.1%), injection site reaction (19.1%), headache (4.1%), increased body temperature (3.8%) and asthenia (3.2%).

The AE reported in association with vaccination were observed in 677 volunteers of age >60 years of age (30.2%). Of these, the commonly reported (>3%) were injection site reaction (12.7%), flu like illness (12.1%), headache (3.5%) and asthenia (3.4%).

By the date of Analysis of study data, 108 episodes of SAE were recorded: 72 in the Vaccine group and 36 in the placebo group. None of the SAEs were reported as related to vaccination.

Table 1: Adverse Drug reactions

Adverse drug reactions (ADRs) are organised by MedDRA System Organ Class (SOC). Within each SOC, preferred terms are arranged by decreasing frequency and then by decreasing seriousness. Frequencies of occurrence of adverse reactions are defined as: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000) and not known (cannot be estimated from available data).

MedDRA SOC	Frequency	Adverse Reaction
Respiratory, chest, and mediastinal disorders	Common	Rhinorrhea, cough
	Uncommon	Oropharyngeal pain, nasal congestion, sore throat, parosmia, nasopharyngitis.
Nervous system disorders	Common	headache
	Uncommon	Impaired sense of taste, doubtfulness
	Rare	Dizziness, syncope
Gastrointestinal disorders	Uncommon	Nausea, vomiting, dyspepsia, stomachache.
	Common	Myalgia
Musculoskeletal and Connective tissue disorders	Uncommon	Arthralgia, Musculoskeletal pain, pain in the extremities, backache.
General disorders and injection site reactions	Very common	Influenza like illness vaccination site tenderness, Increased vaccination site skin temperature, edema and pruritus
	Common	asthenia, hyperthermia,
	Uncommon	malaise, decreased appetite

Lab test and instrumentation data:

Divergent deviations of immunological status indicators: increased count of T-lymphocytes, increase in the percentage of lymphocytes, decreased count of natural killer cells, increased count of CD4-lymphocytes, decreased count of CD4-lymphocytes, increased count of B-lymphocytes, decreased count of B-lymphocytes, increased count of natural killer cells, increased count of CD8 lymphocytes, increased level of immunoglobulin E (IgE) in the blood, increase in the CD4/CD8 ratio, decrease in the CD4/CD8 ratio, increased level of immunoglobulin A (IgA) in the blood, decrease in the percentage of CD8 lymphocytes.

Abnormalities in the complete blood count: increase in the percentage of lymphocytes, decrease in the hematocrit, increased count of lymphocytes, increase in the erythrocyte sedimentation rate, increased leukocyte count, increased count of monocytes, increased platelet count, decreased count of neutrophils, decreased platelet count.

Deviations in common urine analysis: erythrocytes in the urine.

Most AEs ended in complete abatement, without any consequences. Lab test deviations were not of clinical significance (did not require additional diagnostics or therapy).

India Phase II/III adaptive study (NCT04640233)

In the Multi-Centre Phase II/III Adaptive Clinical Trial is being conducted to assess the safety and immunogenicity of Gam-COVID Vac Combined Vector Vaccine for SARS-Cov-2 Infection in Indian healthy subjects. Of the 1,500 subjects (including 115 subjects > 60 years of age) enrolled in the phase III, 33.1% of the study cohort reported 1,784 AE. No SAE associated with vaccination is reported in this study. The commonly reported adverse events includes injection site pain, pyrexia, malaise, chills, asthenia, myalgia, decreased appetite, arthralgia and headache. Most of these events (88%) were of mild severity and transient (99% resolved by the time of interim data analysis). In subjects with > 60 years of age, 26 (21.8%) subjects reported 60 AE. The commonly reported ones include injection site reaction, fever and headache.

Adverse reactions specific to the use of the vaccine, revealed in clinical trials and studies of other vaccines based on a similar technological platform, are predominantly of mild or medium severity, and may develop during the first or second day following vaccination and usually abate within 3 subsequent days.

The most common include short-term general (a brief flu-like syndrome characterized by chills, fever, arthralgia, myalgia, asthenia, general discomfort, headache) or local (injection site tenderness, hyperemia, swelling) reactions. Non-steroidal anti-inflammatory drugs (NSAIDs) are recommended in case of post-vaccination fever and antihistamines for expressed local reactions.

4.9 Overdose

Overdose cases were not reported.

Considering that the dispensing of product is allowed only for medical institutions, and the vaccination itself is carried out only by qualified medical personnel, the risk of overdose is extremely low. However, it can be assumed that with an accidental overdose, the development of the above toxic and toxic-allergic reactions to a more severe degree is possible. There are no specific antidotes to the product.

Therapeutic measures in this case will include symptomatic therapy in accordance with the indications (antipyretic /NSAID and desensitizing agents), corticosteroids - parenterally for severe toxic-allergic syndrome). The regimen for prescribing drugs should be selected according to the recommendations for use and dosages of this product.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: medical immunobiological vaccine.

ATC code: J07B

5.1 Mechanism of action

The vaccine induces the formation of humoral and cellular immunity against coronavirus infection caused by the SARS-CoV-2 virus.

The mechanism of the drug's action is based on the ability of Ad26 and Ad5-based recombinant viral particles carrying the SARS-CoV-2 S protein gene to transduce efficiently the cells of the vaccinated body; in this case, genetic sequences which code the antigen is delivered to the cells, so the transduced cells start to produce the antigen.

When the first dose (component 1) is administered (intramuscularly), the rAd26-based vector enters the cells of the body leading to the expression of SARS-CoV-2 S protein thus triggering the development of specific SARS-CoV-2 immunity. When the second dose (component 2) is administered (intramuscularly), the rAd5-based vector enters the cells of the body leading to the expression of SARS-CoV-2 S protein thus boosting efficiently the immune response to ensure a pronounced long-lasting immunity against SARS-CoV-2.

5.2 Pharmacodynamic properties

Vaccine effectiveness and immunogenicity were studied in various animal models like mice, hamsters and primates. Hamster studies indicated that vaccination could achieve 100% survival in immunosuppressed hamsters when they are infected with SARS-COV-2 virus. Primate studies indicated that there was significant immunogenicity developed in vaccinated animals in terms of s-glycoprotein (spike protein) specific antibodies, virus neutralizing antibody and CD4/CD8 lymphocyte proliferation.

5.3 Pharmacokinetic properties

Target gene expression and content analysis for adenoviral DNA were evaluated in mice administered both components of the vaccine intramuscularly in thigh muscle. The gene expression peaked on day 2 to day 14 in mice organs. The adenoviral DNAs were found restricted to the thigh muscle (Adenovirus serotype 26 and 5) and local lymphnodes (Adenovirus serotype 5) only. No other pharmacokinetic studies were conducted with the product.

6. NONCLINICAL PROPERTIES

6.1 Systemic toxicity, allergenicity and immunotoxicity

Single-dose general toxicity studies were done on mice (each component separately), rabbits (components 1 and 2 in succession, with a reduced administration interval relative to planned clinical use), primates (components 1 and 2 in succession in a therapeutic dose for humans, with the administration interval that is planned for clinical use). Allergenicity tests were carried out on guinea pigs, and immunotoxicity tests on mice. There were toxicity, allergenicity or immunotoxicity was observed in this study with doses several folds high to the human equivalent dose. Studies conducted in primates also observed that there was no antibody dependent enhance reported in the vaccinated animals when they were exposed to SARS-COV-2 virus.

Version No: 00

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WI-GLOB-PG-0002-2.0

Dimensions: 138-300 mm

Any Comments:

Approval from
CMS / Marketing / Country Manager / Country Regulatory / Customer enclosed (tick as applicable)

6.2 Carcinogenesis, Mutagenesis, Impairment of Fertility
No such studies were conducted with the product.

7. Clinical Studies
Phase I/II Clinical Trial in Russia (NCT04436471)
38 volunteers were recruited in this trial, of which 9 each received either component 1 or 2 and were observed for 28 days thereafter as part of Phase I study. Another 20 volunteers received component 1 followed by 2 at interval of 21 days and were followed up till day 42 (3 weeks after the second dose) as part of Phase II study. Phase I study indicated that both components of the vaccines were highly immunogenic and safe in the volunteers. Phase II indicated that humoral immunogenicity parameters s-glycoprotein (spike protein) specific antibodies and virus neutralizing antibodies increased over the observations at days, 14, 21, 28 and 42 with significantly superior titres to the convalescent plasma for the earlier parameter on days 28 and 42 as well as 100 seroconversion for both parameters by day 42. Cellular immunogenicity parameters of CD4/CD8 lymphocyte proliferation and interferon gamma secretion also increased over days 14 and 28 with 100% volunteers showing response in these parameters on day 28.

Phase III Clinical Trial in Russia (RESIST, NCT04530396)
As per the recent interim analysis, 33,771 volunteers [25,321 received Gam-COVID-Vac combined vector vaccine and 8,450 received placebo in 1:3 proportion] were enrolled in the study, which included subjects aged 18 to 92 years old (43.9±12 years), 33.6% females, 8.9% subjects > 60 years of age and 22.8% subjects with comorbidities.

Earlier interim analysis, which was published in Lancet. indicated that amongst 18,695 volunteers receiving both vaccine doses, there were 78 cases of COVID-19 reported [16 in vaccine arm and 62 in Placebo arm] from day 21 onwards with efficacy calculated at 91.6% (95% Confidence interval 85.6% - 95.2%). There were no significant differences in the efficacy across age groups or genders. In terms of moderate to severe COVID-19 cases, all 20 cases were reported in placebo arm indicating 100% protection against such disease. While considering the 60 COVID-19 cases reported from day 28 onwards (1 week after the second dose), the efficacy was calculated at 91.1% (95% confidence interval 83.8% to 95.1%).

Table 2: Interim Efficacy results of Gam-COVID-Vac

	Vaccine group	Placebo group	Vaccine efficacy	P value
First COVID-19 occurrence from 21 days after dose 1 (day of dose 2)*				
Overall	16/14 964 (0·1%)	62/4902 (1·3%)	91·6% (85·6–95·2)	<0·0001
>60 years	2/1611 (0·1%)	8/533 (1·5%)	91·8% (67·1–98·3)	0·0004
Moderate or severe cases	0/14 964	20/4902 (0·4%)	100% (94·4–100·0)	<0·0001
First COVID-19 occurrence after dose 1†				
Any time after dose 1	79/16 427 (0·5%)	96/5435 (1·8%)	73·1% (63·7–80·1)	<0·0001
From 14 days after dose	130/14 999 (0·2%)	79/4950 (1·6%)	87·6% (81·1–91·8)	<0·0001
First COVID-19 occurrence after dose 2 (28 days after dose 1)*				
All	13/14 094 (0·1%)	47/4601 (1·0%)	91·1% (83·8–95·1)	<0·0001

*Data are n/N (%), unless otherwise stated. *Includes those who received both doses. †Includes participants who received at least one dose.*

In terms of humoral immunogenicity, s-glycoprotein (spike protein) specific antibody data from 980 volunteers (733 from the vaccine arm and 247 from the placebo arm), indicates that by day 42 (3 weeks after the second shot), 98.64% of volunteers in vaccine arm achieved seroconversion (with a geometric mean titre of 9818 fold) as compared to 12.55% (P<0.001) volunteers in placebo arm. As per earlier interim analysis, based on 100 volunteers (72 from the vaccine arm and 28 from the placebo arm), indicates that by day 42 (3 weeks after the second shot), 95.83% of volunteers in vaccine arm achieved seroconversion (with a geometric mean titre of 44.5 fold) as compared to 7.14% (P<0.001) volunteers in placebo arm. Further, on day 28 (1 week after the second dose) vaccinated arm reported significant proliferation of CD4 lymphocytes compared to CD8 lymphocytes and significant increase in interferon gamma secretion compared to placebo arm.

Table 3: Immunological response at day 42 in Russia Phase 3 studies

Immunological parameter	Vaccine
SARS-Cov-2 virus s-protein specific antibodies	**n=733**
Seroconv. rate	98.64%
GMT	9818
SARS-Cov-2 virus neutralizing antibodies	**n = 72**
Seroconv. rate	95.83%
GMT	44.5

India Phase II/III adaptive study (NCT04640233)
Phase II part of the India study enrolled 100 subjects (75 in vaccine arm and 25 in placebo arm) and tested the immunogenicity as well as safety of the vaccine in Indian population. The immunogenicity trends in the Phase II population closely correlated with Russia Phase II results as indicated by serial increase in immunogenicity parameters and similar seroconversion. Based on the same, go-ahead was given to Phase III part by the Drug Controller General (India).

Phase III part of the India study enrolled 1500 subjects (1125 in vaccine arm and 375 in placebo arm), of which 284 subjects are being evaluated for immunogenicity parameters. In terms of humoral immunogenicity, s-glycoprotein (spike protein) specific antibody data from 284 volunteers (213 from the vaccine arm and 71 from the placebo arm), indicates that by day 42 (3 weeks after the second shot), 99.5% of volunteers in vaccine arm achieved seroconversion.

For Viral neutralizing Antibody (VNA) - based on 284 volunteers (213 from the vaccine arm and 71 from the placebo arm), indicates that by day 28 (1 week after the second shot), 82% of volunteers in vaccine arm achieved seroconversion (with a geometric mean titre of 94.66 fold).

Further, on day 28 (1 week after the second dose) vaccinated arm reported significant proliferation of CD4 lymphocytes compared to CD8 lymphocytes and significant increase in interferon gamma secretion compared to placebo arm. These results indicate the Gam-COVID-Vac vaccine is highly immunogenic in Indian subjects in line with the results of Russia study.

Table 4: Immunological response after 2nd dose in India Phase III Studies

Immunological parameter	Gam-COVID-Vaccine	
	Day 28	Day 42
SARS-Cov-2 virus s-protein specific antibodies	**n = 210**	**n = 206**
Seroconv. rate	97.1%	99.50%
GMT	2535.08	8327.99
SARS-Cov-2 virus neutralizing antibodies	**n = 210**	**n = 206**
Seroconv. rate	82.0%	81.6%
GMT	94.66	88.50

8. DESCRIPTION
Component I. Frozen solution. It is a dense, hardened, whitish mass. After thawing: homogeneous colorless or yellowish slightly opalescent solution.
Component II. Frozen solution. It is a dense, hardened, whitish mass. After thawing: homogeneous colorless or yellowish slightly opalescent solution.

Characteristics: The vaccine is obtained by biotechnology, which does not use the SARS-CoV-2 virus pathogenic for humans. The product consists of two components: component I and component II. Component I includes a recombinant adenovirus vector based on human adenovirus serotype 26 carrying the gene for the S-protein of the SARS-CoV-2 virus; component II includes a vector based on human adenovirus serotype 5 carrying the protein S gene of the SARS-CoV-2 virus.

9. Pharmaceutical particulars
9.1 Incompatibilities
The product should not be mixed with any other medicinal products or active immunizing agents.

9.2 Shelf-life
6 months. Do not use beyond the shelf life.

9.3 Packaging information
Container Closure System:
Gam-COVID-Vac is presented as Single dose (0.5 mL) of Component I and Component II in ampoule (type I glass). Each ampoule contains 1 dose (0.5 mL).

9.4 Storage and handling instructions
Store in a light-proof place at a temperature of -18°C or below.
Store in a thawed state at room temperature (15-25°C) for no more than 2 hours. Discard any unused contents after this period. Re-freezing is not allowed.
Keep out of reach of children.

Disposal: Any unused vaccine or waste material should be disposed of in accordance with local requirements.

10. Patient Counselling Information
For the prevention of the novel Coronavirus infection (COVID-19) in adults aged over 18, when given in two separate doses three weeks apart.
Day 0: Component I (0.5 ml) & Day 21: Component II (0.5 ml)

How to use Sputnik V.
The vaccination 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.

Method of administration:
The vaccine is intended for intramuscular injection only. Intravenous injection of the product is strictly prohibited. The vaccine is injected into the deltoid muscle (the upper third of the outer shoulder). If it is impossible to inject into the deltoid muscle, the product is injected into the vastus lateral muscle.

Do not take Sputnik V:
If you have
- hypersensitivity to any component of a vaccine or a vaccine containing similar components
- history of severe allergic reactions
- acute infectious and non-infectious diseases, exacerbation of chronic diseases - vaccination is carried out 2-4 weeks after recovery or remission. In case of mild ARVI, acute infectious diseases of the gastrointestinal tract, vaccination is carried out after the temperature has returned to normal;
- during pregnancy
- 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

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).

Pregnancy or breastfeeding
The product is not for use during pregnancy, since its effectiveness and safety during this period have not been studied.

Possible side effects
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 100 people)
- 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.**

11. Details of manufacturer
The Gamaleya National Center of Epidemiology and Microbiology of the Ministry of Health of the Russian Federation
Manufactured at: GENERIUM Joint-Stock Company (GENERIUM JSC), 273 Zavodskaya Street, Volginsky, Petushinsky District, Vladimir Region, 601125 (Russia)
Fill Finish & Packed at: Open Joint Stock Company Pharmstandard-Ufa Vitamin Plant (d), 28, Khudayberdina Street., Ufa, Republic of Bashkortostan, 450077, Russia

Imported and marketed in India by:
M/s. Dr. Reddy's Laboratories Limited, Survey No. 41, Bachupally Village, Bachupally Mandal, Medchal - Malkajgiri(Dist.), Hyderabad – 500090, Telangana, INDIA.
™ Trademark under registration

12. Details of permission or licence number with date
Import licence number: RC/BIO-000193-001 dated 13th April 2021

13. Date of revision
May 2021

HEALTH CARE PROFESSIONALS ARE ASKED TO REPORT ANY SUSPECTED ADVERSE EVENT BY ENTERING IN COWIN APP.
ANY SUSPECTED ADVERSE EVENT CAN ALSO BE REPORTED VIA TOLL FREE NO.1800-180-3204/PvPI ADR APP/SUSPECTED ADRF OR MOR TO DR . REDDY'S DESIGNATED PERSONNEL VIA TOLL FREE NO. 18004250014 OR
EMAIL customerservices@drreddys.com.

Dr.Reddy's

Version No: 00

PANTONE CODES	
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WI-GLOB-PG-0002-2.0

Dimensions: 138-300 mm

Any Comments:

Approval from
CMS / Marketing / Country Manager / Country Regulatory / Customer enclosed (tick as applicable)