SPUTNIK LIGHT™

A vector vaccine for the prevention of the coronavirus infection induced by the SARS-CoV-2 virus

The drug is registered using the registration procedure for drugs intended for use in the situation of a threatened emergency or emergency response. The Instruction is based on limited clinical data on the use of the product and will be updated as new data becomes available. The product may only be administered in healthcare institutions authorized to vaccinate the population under the established procedure.

1. NAME OF THE MEDICINAL PRODUCT

A vector vaccine for the prevention of the coronavirus infection induced by the SARS-CoV-2 virus (Sputnik Light)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per dose (0.5 ml):

Active substance: recombinant HAd26 particles containing the protein S gene of the SARS-CoV-2 virus, (1.0±0.5) x 10^{11} particles per dose.

Excipients: tris-(hydroxymethyl)aminomethane - 1.21 mg, sodium chloride -2.19 mg, sucrose - 25.0 mg, polysorbate 80 - 250 µg, magnesium chloride hexahydrate - 102.0 µg, EDTA-disodium salt dihydrate – 19.0 µg, ethanol 95% - 2.50 µl, water for injections about 0.5 ml or less.

3. PHARMACEUTICAL FORM

A solution for intramuscular injection. 0.5 ml/dose

4. CLINICAL PARTICULARS

4.1 Indications:

Sputnik Light vaccine is indicated for

The prevention of the novel coronavirus infection (COVID-19) in adults aged over 18 years

4.2 Posology and Administration:

Sputnik Light Vector vaccination course consists of one 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 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, take a vial out of the freezer and keep at room temperature (15-25oC) until completely thawed with no visible frozen inclusions. The vial may be held in hands to help it thaw.

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

Remove the protective plastic overlay from the vial and treat the rubber stopper with an alcohol wipe.

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^{o}C) for upto 2 hours. Unused contents after this period must be discarded.

4.3 Contraindications:

If you have

- hypersensitivity to any component of a vaccine or a vaccine containing similar components
- if you are suffering from common cold, runny nose, fever, cough, bodyache or loose motions etc
- age less than 18 years (due to lack of data on efficacy and safety).

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

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 Interaction with other medicinal products

No interaction studies have been performed.

Concomitant administration of Sputnik light with other vaccines has not been studied

4.6. Fertility, Pregnancy and Lactation

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

Administration of sputnik light Vaccine in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus

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

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 I/II Clinical Study (NCT04713488)

A safety analysis in phase I-II study conducted in Russia included 110 volunteers (all volunteers who were administered a dose of the study drug). A total of 181 AEs in 80 (72.73%) volunteers were recorded during this study. All the AE were non-serious. No SAEs were reported in this study. Most AEs were mild (173 AEs); 7 were moderate and one severe (hyperthermia).

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.

Less common ones include nausea, dyspepsia, loss of appetite, occasionally - enlarged regional lymph nodes. Some patients may develop allergic reactions, short-term elevated liver transaminase levels, elevated serum creatinine and creatine phosphokinase levels.

Within the Sputnik Light safety, tolerability, and immunogenicity clinical trials conducted to date the following AEs have been registered:

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 common and very 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.

Adverse events presented below are grouped by organ systems and frequency. Frequency is defined as follows: very common (≥1/10), common (≥1/100 and < /10), uncommon (≥1/1000 and <1/100), rare (≥1/10000 and <1/1000), very rare (≥1/10000, including single cases). The frequency categories have been defined based on clinical trials of the drug.

Common events are: nausea, dyspepsia, loss of appetite, very rare – enlarged regional lymph nodes. Some patients may develop allergic reactions, short-term elevated liver transaminase levels, elevated serum creatinine and creatine phosphokinase levels.

MedDRA SOC	Frequency	Adverse Reaction

Respiratory, chest, and mediastinal disorders	Common	Oropharyngeal pain, nasal congestion, sore throat, rhinorrhea.
Nervous system disorders	Common	Headache, asthenia
	Rare	Dizziness, syncope
Gastrointestinal disorders	Common	Nausea, vomiting, dyspepsia,
General disorders and injection site reactions	Very common and Common	hyperthermia, vaccination site tenderness, edema and pruritus, asthenia, pain, malaise, pyrexia, increased vaccination site skin temperature, 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.

Abnormalities in common urine analysis: erythrocytes in the urine.

Most AEs ended in complete recovery, with no consequences. Lab test deviations were not of clinical significance (did not require additional diagnostics or therapy).

Ongoing Phase III Clinical Trial (NCT04741061)

In the interim analysis of ongoing phase 3 clinical trial safety parameters were assessed for all subjects (4194 (100.0%)) included in the study.

Analysis showed that 1,659 (39.6%) volunteers developed AEs after the vaccine/placebo was administered.

The vast majority of AEs which were related to vaccination were mild in both groups. In the Sputnik Light group, AEs related to vaccination characterized by mild severity were recorded in 983 (31.2%) volunteers; AEs of moderate severity occurred in 116 (3.7%) volunteers; severe AEs occurred in 7 (0.0%) volunteers; there were no life-threatening AEs or SAEs related to vaccination of volunteers in the Sputnik Light group.

There were no fatal SAEs related to vaccination of volunteers in the Sputnik Light group.

The most frequently encountered adverse events that developed among the volunteers in the Sputnik Light group were- Reaction at the injection site in (12.6%), Flu-like illness (8.7%), Pain at the injection site (7.9%), Asthenia (7.2%), Hyperthermia (5.7%).

Table 1: Adverse events reported in ≥1% subjects by preferred term (PT)

MedDRA System Organ Class MedDRA Preferred Term	Sputnik Light (N=3,148)	Placebo (N=1,046)
Volunteers with AEs	**1,297 (41.2%)**	**362 (34.6%)**
General disorders and reactions at the injection site (1,870 AE episodes)		
Reaction at the site where study drug was administered	396 (12.6%)	49 (4.7%)
Influenza-like illness	275 (8.7%)	45 (4.3%)
Asthenia	227 (7.2%)	67 (6.4%)
Pain at the injection site	248 (7.9%)	25 (2.4%)
Hyperthermia	178 (5.7%)	23 (2.2%)
Chest pain	54 (1.7%)	13 (1.2%)
Chills	55 (1.7%)	6 (0.6%)
Sensation of fever	37 (1.2%)	12 (1.1%)
Nervous system disorders (626 AE episodes)		
Headaches	315 (10.0%)	78 (7.5%)
Dizziness	62 (2.0%)	26 (2.5%)
Disorder of the involuntary nervous system	48 (1.5%)	11 (1.1%)
Respiratory, thoracic, and mediastinal disorders (321 AE episodes)		
Rhinorrhea	68 (2.2%)	32 (3.1%)
Pain in the oropharynx	50 (1.6%)	23 (2.2%)
Cough	46 (1.5%)	13 (1.2%)
Muscular, skeletal, and connective tissue disorders (264 AE episodes)		
Myalgia	88 (2.8%)	13 (1.2%)
Arthralgia	70 (2.2%)	10 (1.0%)
Circulatory system disorders (160 AE episodes)		
Hypertension	70 (2.2%)	31 (3.0%)
Infections and incidents involving invasion (168 AE episodes)		
COVID-19	8 (0.3%)	13 (1.2%)
Skin and subcutaneous tissue disorders (51 AE episodes)		
Hyperhidrosis	9 (0.3%)	11 (1.1%)

Sputnik Light (Component I of Sputnik V) in Seronegative and Seropositive Indian adults and elderly for prevention of SARS-CoV-2 Infection (DRL-SPL-005)

In a Phase III, open label, uncontrolled, multicentre, bridging study to evaluate immunogenicity and safety of single dose of Sputnik Light (Component I of Sputnik V) in Indian adults and elderly for prevention of SARS-CoV-2 Infection, safety was analyzed for 179 patients. No SAEs were reported till Day 42. All the 90 AEs reported in 60 subjects resolved completely.

The most frequently encountered adverse events that developed among the volunteers in the Sputnik Light group were- Pain at the injection site (16.2%), Asthenia (3.4%), Pyrexia (14.5%), Myalgia (3.4%).

Table 2: Adverse events reported in subjects by preferred term (PT)

SOC/PT, n(%)	**Overall(N=179)**
OVERALL	**60 (33.5%)**
General disorders and administration site conditions	**51 (28.5%)**
Asthenia	6 (3.4%)
Chills	3 (1.7%)
Injection site erythema	1 (0.6%)
Injection site pain	29 (16.2%)
Malaise	2 (1.1%)
Pain	1 (0.6%)
Pyrexia	26 (14.5%)
Vaccination site swelling	2 (1.1%)
Musculoskeletal and connective tissue disorders	**8 (4.5%)**
Arthralgia	1 (0.6%)
Myalgia	6 (3.4%)
Pain in extremity	1 (0.6%)
Nervous system disorders	**5 (2.8%)**
Dizziness	1 (0.6%)
Headache	4 (2.2%)
Respiratory, thoracic and mediastinal disorders	**2 (1.1%)**
Cough	2 (1.1%)
Gastrointestinal disorders	**1 (0.6%)**
Vomiting	1 (0.6%)
Infections and infestations	**1 (0.6%)**
Nasopharyngitis	1 (0.6%)

Psychiatric disorders	**1 (0.6%)**
Insomnia	1 (0.6%)
n: Subject Count, E:Event Count, NE: Not Estimable.	

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 these products.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: medical immunobiological vaccine.

ATC code: J07B

5.1 Pharmacodynamic properties

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 sputnik light 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.

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.

Immunological efficacy

The immunological properties and safety of the vaccine have been studied in various clinical trials in adult volunteers of both sexes over the age of 18.

An intermediate immunogenicity review revealed that the vaccine had formed an immune response in the subjects. Seroconversion was registered in 96.88% healthy volunteers on Day 28.

Persons with existing immunity to coronavirus were found to have a marked growth of antibody levels on the 10th day after inoculation which may suggest an opportunity to use the drug for vaccinating people who have had COVID-19 and have a lowered antibody titer with the aim of preventing a relapse of the disease.

A single-shot immunization in 100% healthy volunteers (all the 30 subjects whose cell mediated immunity had been studied) formed a cell immune response to SARS-Cov2 S-protein.

The protective antibody titer is currently unknown. Duration of protection is not known.

5.2 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 only. No other pharmacokinetic studies were conducted with the product.

5.3 Preclinical Safety data

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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No such studies were conducted with the product.

5.4 Clinical Studies

Phase I/II Clinical Study (NCT04713488)

An Phase I/II, open study on the safety, tolerability, and immunogenicity study of "Sputnik Light" to help prevent the coronavirus infection caused by the SARS-CoV-2 virus was conducted in Russia in 110 volunteers. Immunological efficacy results demonstrates that:

- 100% seroconversion in seronegative volunteers (GMT 1648) and 92.86% seroconversion in seropositive volunteers (GMT 19986.16) in terms of SARS-Cov-2 s-glycoprotein specific antibodies on Day 42
- 94.39% seroconversion in seronegative volunteers (GMT 14.57) and 100% seroconversion in seropositive volunteers (GMT 751) in terms of SARS-Cov-2 virus neutralising antibodies on Day 42

- Strong cellular immune response on day 10 as indicated by CD4 dominant mitogen stimulated lymphoproliferation and >20 fold rise in IFN gamma induction.

Ongoing Phase III Clinical Trial (NCT04741061)

A Phase III Clinical Trial to evaluate the efficacy, safety and tolerance of using the Sputnik Light vector vaccine in parallel groups to help prevent the infection caused by the SARS-CoV-2 infection when compared to a placebo is ongoing in Russia. Interim analysis of Phase III Clinical Trial on efficacy, safety and immunogenicity is ongoing in 4194 volunteers showed that

- Sputnik Light vaccine provides efficacy of 65.4% against COVID-19 21 days after immunization.
- A one-time immunization given using the Sputnik Light vaccine causes the formation of antigen-specific IgG antibodies to the S protein with high seroconversion of 94.7% for seronegative individuals by day 42 after vaccination. On day 42 after vaccination, the subjects in the Sputnik Light group showed a significant increase in the titer of virus-neutralizing antibodies (VNAs) in the blood serum, with an increase from 4.3 to 76.4 ($p<0.0001$), i.e. 17.7 times, which indicates the formation of a specific immune response.
- A single immunization given using the Sputnik Light vaccine is capable of reducing the severity of the cases involved when compared to the Placebo group. There were no severe cases that occurred in the Sputnik Light group, and 2 cases were recorded in the placebo group.

Parameter	**Sputnik Light**	**Placebo**	
SARS-Cov-2 Glycoprotein antibodies *(N = 300, 231 on Sputnik Light and 69 on placebo)*			
Overall GMT at Day 42	4762.2 (3531.0; 6422.8)	23.7 (9.9; 56.3)	GMTR 201.2 (110.2; 367.6), P < 0.0001
Overall seroconversion at Day 42	224/231 (97.0%)	31/69 (44.9%)	P < 0.001
Baseline seronegative GMT at Day 42	1506.9* (1026.9; 2211.1)	2.4 (1.1; 5.0)	GMTR 636.5 (326.4; 1241.2), P < 0.0001
Baseline seronegative seroconversion at Day 42	126/133 (94.7%)	5/42 (11.9%)	P < 0.001
Baseline seropositive GMT at Day 42	22699.7 (17691.8; 29125.2)	849.9 (431.6; 1673.6)	GMTR 26.71 (16.39; 43.53), P < 0.0001
Baseline seropositive seroconversion at Day 42	98/98 (100.0%)	26/27 (96.3%)	P = 0.216
SARS-Cov-2 Neutralizing antibodies *(N = 50, 39 on Sputnik Light and 11 on placebo)*			
Overall GMT at Day 42	76.4 (32.7; 178.5)	4.2 (1.2; 14.3)	GMTR 18.37 (4.45; 75.91), P = 0.0012
Baseline seronegative GMT at Day 42	8.8[@] (4.0; 19.4)	1.8 (0.7; 4.6)	GMTR 4.96 (1.64; 15.00), P = 0.0204
Baseline seropositive GMT at Day 42	740.6 (470.6; 1165.4)	40.0 (1.3; 1252.2)	GMTR 18.51 (6.38; 53.73), P =0.0001

Sputnik Light (Component I of Sputnik V) in Seronegative and Seropositive Indian adults and elderly for prevention of SARS-CoV-2 Infection (DRL-SPL-005)

In a Phase III, open label, uncontrolled, multicentre, bridging study to evaluate immunogenicity and safety of single dose of Sputnik Light (Component I of Sputnik V) in Indian adults and elderly for prevention of SARS-CoV-2 Infection, data was analyzed to see the geometric mean titers and seroconversion rate for glycoprotein-specific antibodies and viral neutralizing antibodies at D28, D42 & D90 in subjects who were seronegative and seropositive at baseline.

Table 3: Summary of Geometric Mean SARS-CoV-2 glycoprotein-specific antibodies and seroconversion rates– Immunogenicity Analysis Set

SARS-CoV-2 glycoprotein-specific antibodies, [1]	India (Seronegative) (N=25)	India (Seropositive) (N=154)	India Overall (N=179)
Visit 1 ((Baseline)			
n	25	154	179
GMT (95% CI)	1.00 (1.00:1.00)	2674.95 (2220.35:3222.64)	888.47 (610.69:1292.58)
Visit 3 (Day 28)			
n	25	152	177
GMT (95% CI)	3929.40 (2323.45:6645.39)	15012.55 (12836.81:17557.07)	12423.19 (10560.69:14614.17)
GMTR (Post vaccination GMT/ Pre-vaccination GMT)	3929.40	5.61	13.98
Seroconverted	25(100.0%)	79(52.0%)	104(58.8%)
Not Seroconverted	0(0.0%)	73(48.0%)	73(41.2%)
Visit 4 (Day 42)			
n	25	152	177
GMT (95% CI)	15555.59 (10541.06:22955.59)	32187.79 (29850.92:34707.59)	29045.97 (26575.87:31745.67)
GMTR (Post vaccination GMT/ Pre-vaccination GMT)	15555.59	12.03	32.69
Seroconverted	25(100.0%)	118(77.6%)	143(80.8%)
Not Seroconverted	0(0.0%)	34 (22.4%)	34(19.2%)
Visit 5 (Day 90)			
N	23	145	168
GMT (95% CI)	30315.19 (20974.39:43815.86)	42809.81 (40540.00:45206.91)	40834.24 (38126.92:43733.80)
GMTR (Post vaccination GMT/ Pre-vaccination GMT)	30315.19	16.0	45.96
Seroconverted	23(100.0%)	119(82.1%)	142(84.5%)
Not Seroconverted	0(0%)	26(17.9%)	26(15.5%)

Table 4: Summary of Geometric Mean SARS-CoV-2 Virus Neutralizing antibodies and seroconversion rates – Immunogenicity Analysis Set

SARS-CoV-2 viral Neutralizing antibodies	India (Seronegative) (N=25)	India (Seropositive) (N=154)	India Overall (N=179)
Visit 1 ((Baseline)			
n	23	152	175
GMT (95% CI)	8.60 (5.39:13.72)	67.87 (52.86:87.18)	51.75 (40.66:65.85)
Visit 3 (Day 28)			
n	22	141	167
GMT (95% CI)	109.63 (60.71:197.98)	438.32 (384.72:499.38)	368.50 (318.57:426.26)
GMTR (Post vaccination GMT/ Pre-vaccination GMT)	12.73	6.46	75.12
Seroconverted	16(72.7%)	87(61.7%)	103(63.2%)
Not Seroconverted	6(27.3%)	54(38.3%)	60(36.8%)
Visit 4 (Day 42)			
n	23	150	177
GMT (95% CI)	57.43 (27.09:121.76)	294.46 (243.25:356.45)	242.32 (198.57:295.73)
GMTR (Post vaccination GMT/ Pre-vaccination GMT)	6.68	4.34	4.68
Seroconverted	12(52.2%)	82(54.7%)	94(54.3%)
Not Seroconverted	11(47.8%)	68(45.3%)	79(45.7%)
Visit 5 (Day 90)			
N	23	146	171
GMT (95% CI)	87.57 (45.94:166.91)	295.19 (249.11:349.78)	251.93 (211.56:300.01)
GMTR (Post vaccination GMT/ Pre-vaccination GMT)	10.18	4.35	4.87
Seroconverted	16(69.6%)	81(55.5%)	97(57.4%)
Not seroconverted	7(30.4%)	65(45.5%)	72(42.6%)

The GMT titer for S-glycoprotien and VNA rose to much higher levels in patients who were seropositive at baseline as compared to patients who were baseline seronegative. This is expected as the baseline titres were already on higher side for seropositive subjects.

For subjects who were seronegative at baseline showed 100% seroconversion at D28, D42 and D 90 for Spike protein. approx. 72.7% and 52.2%, 69.6% seroconversion was observed at D28, D42and D90 for VNA, respectively. Seroconversion in general was on the lower side for patients who were baseline seropositive owing to their higher baseline titres as the criteria for 4-fold rise over the baseline was difficult to be met.

6. PHARMACEUTICAL PARTICULARS

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 Recombinant adenoviral particles of serotype 26 containing the protein S gene of the SARS-CoV-2 virus

6.1 List of Excipients

Excipients: tris-(hydroxymethyl)aminomethane - 1.21 mg, sodium chloride -2.19 mg, sucrose - 25.0 mg, polysorbate 80 - 250 µg, magnesium chloride hexahydrate - 102.0 µg, EDTA-disodium salt dihydrate – 19.0 µg, ethanol 95% - 2.50 µl, water for injections Q.s.to 0.5 ml.

6.2 Incompatibilities

The product should not be mixed with any other medicinal products or active immunizing agents.

6.3 Shelf-life

Frozen drug: 6 months. Do not use after expiry date.

6.4 Special precautions for storage

Store in a dark 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.

6.5 Nature and contents of container

Primary packaging: Sputnik Light is presented in Single dose glass ampoule (0.5 mL). Each ampoule contains 1 dose (0.5 mL).

6.6 Instructions for use, handling and disposal

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

7. MARKETING AUTHORIZATION

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

TM Trademark under registration

8. MARKETING AUTHORISATION NUMBER (S)

Import Permission No. IMP/BIO/22/000008

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

30 March 2022

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.

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 LIGHT 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 LIGHT 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 LIGHT Vaccine, which you may receive because there is currently a pandemic of COVID-19 disease.

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

Please read this Fact Sheet for information about the Dr Reddy's laboratories COVID-19 Vaccine (SPUTNIK LIGHT Vaccine). Talk to Vaccinator/ Officer supervising your vaccination if you have any questions.

It is your choice to receive the Dr Reddy's Laboratories COVID-19 Vaccine ((SPUTNIK LIGHT Vaccine).

The Dr Reddy's Laboratories COVID-19 Vaccine (SPUTNIK LIGHT Vaccine) is solution for injection. The vaccination is carried out as an intramuscular injection, 0.5 ml/dose.

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

The SPUTNIK LIGHT Vaccine 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 in humans. 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 LIGHT VACCINE?

Sputnik Light Vaccine is a 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 LIGHT 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 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 LIGHT VACCINE?

Sputnik Light Vaccine has been approved for restricted use in emergency situation in individuals over 18 years.

WHO SHOULD NOT GET THE SPUTNIK LIGHT VACCINE?

If you have

- hypersensitivity to any component of a vaccine or a vaccine containing similar components
- if you are suffering from common cold, runny nose, fever, cough, bodyache or loose motions etc
- age less than 18 years (due to lack of data on efficacy and safety).

WHAT ARE THE INGREDIENTS IN THE SPUTNIK LIGHT VACCINE?

Composition per dose (0.5 ml):

Active substance: recombinant serotype 26 adenoviral particles, containing the SARS-CoV-2 protein S gene, (1.0±0.5) x 10^{11} particles per dose.

Excipients: tris-(hydroxymethyl)aminomethane - 1.21 mg, sodium chloride -2.19 mg, sucrose - 25.0 mg, polysorbate 80 - 250 µ, magnesium chloride hexahydrate - 102.0 µg, EDTA-disodium salt dihydrate – 19.0 µg, ethanol 95% - 2.5 µl, water for injections about 0.5 ml or less.

HOW IS THE SPUTNIK LIGHT VACCINE GIVEN?

The Sputnik Light Vaccine is intended for intramuscular injection only. Intravenous injection of the product is strictly prohibited. The vaccine is injected into the upper third of the outer shoulder. If it is impossible to inject into the deltoid muscle, the product is injected into the lateral part of thigh muscle.

You will monitored by your health care professional for 30minutes after taking the vaccine.

HAS THE SPUTNIK LIGHT VACCINE BEEN USED BEFORE?

The Sputnik Light Vaccine 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 LIGHT VACCINE?

You are being given Sputnik light as the booster dose. In ongoing clinical trials, the Sputnik Light Vaccine has been shown to prevent COVID-19 disease following a single dose also. The duration of protection against COVID-19 disease is currently unknown.

You may get protective immune response within 1 to 3 weeks after receiving the vaccine. Hence, you must practice the COVID-19 precautions recommended to prevent SARS-COV-2 infection till 3 weeks after the vaccine administration.

As with all the other vaccines, not every vaccinated individual may develop protective immune response.

WHAT ARE THE RISKS OF THE SPUTNIK LIGHT VACCINE?

Side effects that have been reported with the Sputnik Light 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 upto 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),
- Indigestion (dyspepsia),
- loss of appetite,

Rare

- enlarged regional lymph nodes
- allergic reactions

- dizziness
- temporary loss of consciousness caused by a fall in blood pressure (syncope)

Serious and unexpected side effects may occur.

SPUTNIK LIGHT 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 LIGHT VACCINE?

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

CAN I RECEIVE THE SPUTNIK LIGHT VACCINE WITH OTHER VACCINES?

Sputnik Light Vaccine is a single shot vaccine. Moreover there is no information on the use of the Sputnik Light Vaccine with other vaccines for added benefit.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

Administration of sputnik Light in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Talk to your health care Provider before taking the vaccine.

Sputnik light can be taken while breast feeding also.

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

No. The Sputnik Light Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19 infection.

Sputnik Light is a 'Vector Vaccine' containing recombinant serotype 26 adenoviral particles These 'vectors' are stripped of any disease-causing genes and sometimes also genes that can enable them to replicate, meaning they are now harmless.

KEEP YOUR VACCINATION CARD

When you get vaccinated, 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

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

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