Sputnik V

1. INTRODUCTION

Sputnik V (Gam-COVID-Vac) is a combined vector vaccine for the prevention of coronavirus infection caused by the SARS-CoV-2 virus. It is a two-component vaccine consisting of two separate doses, each containing 0.5 ml of the vaccine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Component I:

Active substances:
- Recombinant adenovirus serotype 5 particles containing the SARS-CoV-2 gene
- Adenovirus serotype 26 particles containing the SARS-CoV-2 gene
- Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 gene

Excipients:
- Tris (hydroxymethyl) aminomethane - 1.21 mg
- Sodium chloride - 2.19 mg
- Sucrose - 15 mg

Component II:

Active substances:
- Recombinant adenovirus serotype 5 particles containing the SARS-CoV-2 gene
- Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 gene

Excipients:
- Tris (hydroxymethyl) aminomethane - 1.21 mg
- Sodium chloride - 2.19 mg
- Sucrose - 15 mg

3. DOSAGE FORM AND STRENGTH

Gam-COVID-Vac (Component I) - 0.5 ml/dose & (Component II) - 0.5 ml/dose

4. DESCRIPTION

Sputnik V is a combined vector vaccine consisting of two separate doses of 0.5 ml each. The vaccine is administered intramuscularly, with Component I on Day 0 and Component II on Day 21.

5. PHARMACOLOGICAL PROPERTIES

5.1 Systemic toxicity, allergenicity and immunotoxicity

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 this rodent model. Pronounced long-lasting immunity against SARS-CoV-2 was observed in vaccinated hamsters.

5.2. Undesirable effects

Adverse reactions specific to the use of the vaccine, revealed in clinical trials and studies of other vaccines:

- Infection site reaction
- Inflammation
- Pain
- Temporary neurological symptoms
- Generalized flu-like syndrome
- Rash

5.3. Overdosage

It can be assumed that with an accidental overdose, the development of the above toxic and toxicological effects is impossible.

5.4. Incompatibilities

There is no interaction of Gam-COVID-Vac with other drugs. This is due to the fact that the vaccine contains no substances that are capable of interacting with other substances.

5.5. Stability

Sputnik V is a stable drug and does not require special storage conditions.

6. USE IN SPECIFIC GROUPS

6.1 Systemic toxicity, allergenicity and immunotoxicity

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6.6. Contraindications

- Pregnancy
- Lactation
- Allergy to any component of the vaccine
- Known or anticipated antibody-dependent enhancement reaction

6.7. Effectiveness and efficacy of the two components

The vaccine is effective in preventing coronavirus infection caused by the SARS-CoV-2 virus. The vaccine is highly immunogenic, with high levels of neutralizing antibodies observed in vaccinated individuals.

6.8. Side effects

The most common side effects observed in clinical trials were:

- Injection site reaction
- Local pain
- Generalized flu-like syndrome
- Headache

6.9. Stability

Sputnik V is a stable drug and does not require special storage conditions.

7. PHARMACOKINETICS

Through the injection of the vaccine, the rAd5-based vector enters the cells of the body leading to the transduction of the host cell and the expression of the antigen.

8. CLINICAL EFFECTIVENESS

The vaccine induces the formation of humoral and cellular immunity against coronavirus infection. The vaccine was shown to be effective in preventing COVID-19 in various clinical trials.

9. PHARMACODYNAMICS

There is no specific pharmacokinetic data available for the vaccine.

10. REFERENCES


11. ARTWORK APPROVAL FORM

Page: 1 of 2

Version: 0.0

Dimensions: 130 x 200 mm

File names: ARTWORK APPROVAL FORM - Sputnik V.pdf

Approval from:
- Mark V \n- Country Manager / Country Regulatory / Customer (for all applicable).

Date: [Signature]

Sputnik V is a combined vector vaccine for the prevention of coronavirus infection caused by the SARS-CoV-2 virus. It is a two-component vaccine consisting of two separate doses, each containing 0.5 ml of the vaccine. The vaccine is administered intramuscularly, with Component I on Day 0 and Component II on Day 21. The vaccine is highly immunogenic, with high levels of neutralizing antibodies observed in vaccinated individuals.
The product should not be mixed with any other medicinal products or active immunizing agents.

6 months. Do not use beyond the shelf life.

9.3 Packaging information

Container Closure System: (type I glass). Each ampoule contains 1 dose (0.5 mL).

9. Pharmaceutical particulars

11. Contact Information

For customers/questions please contact:

Generium JSC
Telephone: +7 499 285 04 49
Email: info@generium.ru
Website: www.generium.ru

5. Pharmaceutical particulars

5.9 Special precautions for storage

Store below 25 °C.

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