

Staphylococcal Bacteriophage

Product description

Name of the pharmaceutical product (Patentable):

Staphylococcal bacteriophage

Georgian pharmaceutical product registration number: **R-022876**

Composition:

Staphylococcal bacteriophage is a filtrate of the purified phage lysate active against *Staphylococcus aureus* strains with titer no less than 10^7 ml⁻¹

Inactive ingredients: Bacteriological growth medium, standard sodium saline. Chinazolin as a conservator.

Description:

Preparation is transparent, colorless liquid.

Pharmaco-therapeutical group:

Specific antibacterial solution.

Pharmacological actions:

Staphylococcal bacteriophage leads to a specific lysis of bacteria belonging to the *Staphylococcus aureus* species.

Prescription:

Staphylococcal bacteriophage is used in the treatment and prophylaxis of infections caused by *Staphylococcal* bacteria.

Indications:

Preparation is directed to use for treatment of infections caused by staphylococci such as:

- Upper airways, nose, throat, lung, ear (pharyngitis, tonsillitis, tracheitis, bronchitis, pleuritis, pneumonia, inflammation of middle ear) infectious diseases;
- Surgical infections (infectious wound, infected burn, abscess, phlegmona, furuncle, carbuncle, paraproctitis, mastitis, bursitis, osteomyelitis, panaricium);
- Urogenital infections (urethritis, cystitis, pyelonephritis, colpitis, endometritis);
- Enteric infections (gastroenteric colitis, cholecystitis);
- Purulent-septic infections in newborn (omphalitis, pyoderma, conjunctivitis, gastroenteric colitis and others)
- Other *Staphylococcal* infections

Usage and dosage:

Staphylococcal bacteriophage is used for prophylaxis and treatment of post-operational and infected wounds, as well as hospital staphylococcal infections, confirmed as an epidemiological indicator.

Preparation can be used through different applications, including: *per os*, treatment of wounds by drainage and application, *per rectum*, through applications directly inside the ear, throat, nose, urinary tract cavities.



**STAPHYLOCOCCAL
BACTERIOPHAGE**

STERILE PURIFIED SOLUTION FOR TOPICAL AND ORAL USE

10 ml x 5

Phages active against (pfu/ml)
Staphylococcus (10⁷)

Preparations developed by
GEORGE ELIAVA INSTITUTE
OF BACTERIOPHAGES, MICROBIOLOGY AND VIROLOGY



Recommended doses of Staphylococcal bacteriophage are as follows:

Age	Type of application and doses	
	Per os (ml)	Per rectum (ml) (after cleaning with enema)
Infants 0-6 months	5	5-10
Kids 6-12 months	10	10-20
Kids 1-3 years	15	20-30
Children 3-8 years	15-20	30-40
Children older than 8 years, adults	20-30	40-50

During Per os application of Staphylococcal bacteriophage in adults and children from age of 3, drinking of 2-3% baking soda solution (one glass, 150-250 ml) is recommended.

In case of infectious abscess, phage is introduced by injection in abscess cavity after evacuation of pus; the volume of used phage should be less than evacuated pus. In case of open abscess, tampon with phage might be used in cavity. -In case of lung abscess, phage is used by trans-thoracal puncture and by catheter in tracheobronchial system. In case of emphysema, the preparation could be used by puncture and drainage. One dose includes 10-20ml of phage during phage application by catheter of tracheobroncheal system, in case of emphysema – the single dose is from 10 ml to 50 ml.

Special Warnings:

Before use, the vial should be well shaken. The contents should be transparent liquid without sediment. The preparation should not be used in case of vials damage or if the liquid inside is non-transparent! Do not store and use the drug after destroying the integrity of the vial!!!

Overdosing:

During the usage of Staphylococcal bacteriophage, overdosing symptoms have not been revealed.

Contradictions:

Usage of Staphylococcal bacteriophage does not have contradictions.

Side effects:

No side effects have been revealed during usage of Staphylococcal bacteriophage.

Usage together with other preparations:

The preparation can be used in parallel or supplemental to other medications. Drinking alcohol during treatment with bacteriophages is not recommended.

Specific categories of patients:

Pregnancy and lactation:

Preparation can be used during pregnancy and lactation period.

Usage in elderly people:

Preparation is used in elderly people.

Effect on drivers and people working with potentially harmful machines:

Usage of bacteriophages does not affect driving skills or skills of other equipment usage.

Packaging:

Staphylococcal bacteriophage is produced in 10 ml vials (5 vials per pack).

Storage conditions and shelf life:

Store at +2C⁰ - +8C⁰ in dry place, protected from direct light.

Shelf life 24 month.

Preparation developed by G. Eliava Institute of Bacteriophages, Microbiology and Virology.

Manufactured by:

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