

Intesti Bacteriophage

Product description

Name of the pharmaceutical product (Patentable):
Intestibacteriophage

Georgian pharmaceutical product registration
number: **R-022601**

Composition:

Intesti bacteriophage is a combined preparation. Intesti bacteriophage is a mix of sterile filtrates of phage lysates active to:

- *Shigella* (*Shigella flexneri* serotype 1,2, 3, 4 and *Shigella sonnei*) titter no less than 10^5 ml⁻¹,
- *Salmonella* (*S. paratype A*, *S. paratype B*, *S. typhimurium*, *S. enteritidis*, *S. cholerae suis*, *S. oranienburg*) titter no less than 10^5 ml⁻¹,
- Different types of *E. coli* titter no less than 10^5 ml⁻¹,
- *Proteus* (*mirabilis* and *vulgaris*) titter no less than 10^5 ml⁻¹,
- *Staphylococcus* (*S. aureus*) titter no less than 10^5 ml⁻¹,
- *Pseudomonas aeruginosa* titter no less than 10^5 ml⁻¹,
- *Enterococcus* titter no less than 10^5 ml⁻¹

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

Description:

Preparation is transparent liquid, with yellow to light brown colour.

Pharmaco-therapeutical group:

Specific antibacterial solution.

Pharmacological actions:

Intesti bacteriophage leads to specific lysis of following bacteria: *Shigella flexneri* (Serotypes 1,2,3,4; *Shigella sonnei*; *Shigella newcastle*; *Salmonella paratyphi A* and *Salmonella paratyphi B*; *Salmonella typhimurium*; *Salmonella enteritidis*; *Salmonella choleraesuis*; *Salmonella oranienburg*; *Escherichia coli*; *Proteus* (*vulgaris*, *mirabilis*); *Staphylococcus aureus*; *Pseudomonas aeruginosa*; *Enterococcus faecalis*.

Prescription:

Intesti bacteriophage is used in the treatment and prophylaxis intestinal infectious diseases caused by enlisted microorganisms.

Indications:

Dysentery; - Salmonellosis; - Dyspepsia.; - Infective colitis; - Enterocolitis; - Dysbacteriosis;

Usage and dosage:

Intesti bacteriophage for treatment purposes is used *per os* with first signs of disease within 5-6 days. Intesti bacteriophage should be used in following doses:



INTESTI BACTERIOPHAGE

ANTIBACTERIAL SOLUTION FOR ORAL USE

10 ml x 5

Bacteriophages active against (titre per ml):

Staphylococcus (10⁵), *Enterococcus*(10⁵), *Proteus*(10⁵), *Shigella*(10⁵),
Salmonella(10⁵), *Escherichia coli*(10⁵), *Pseudomonas aeruginosa*(10⁵)

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



<u>Age</u>	<u>Amount of admissions</u>	<u>Period of admissions</u>
Children up to 3 years of age	5 ml per admission	4 times a day 30 minutes before meal
Children from age of 3 and adults	10 ml per admission	4 times a day 30 minutes before meal

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

In parallel to *per os* admission of Intest ibacteriophage it is recommended to use Intesti bacteriophage *per rectum*, once a day in the amount of 10 ml for children and 20 ml for adults. (*Per rectum* usage is recommended in the evening with enema after emptying stomach)

For prophylaxis use Intesti bacteriophage is recommended:

- In organized groups to prevent spread of infections. During seasonal infections, Intestibacteriophage can be applied once a day in amount of 10-20 ml. Application can be made with the interval of 5 days during 1 month.
- During the rise period of intestinal infections, all patients in the clinics are recommended to go through phage treatment despite diagnoses. Phage application is recommended 2 times with the interval of 5 days. Amount per admission should be 10-20 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 Intesti bacteriophage, overdosing symptoms have not been revealed.

Contradictions:

Usage of Intesti bacteriophage does not have contradictions.

Side effects:

No side effects have been revealed during usage of Intesti 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:

Intest ibacteriophage 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 18 month.

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

Manufactured by:

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