

Ministry of Health and Social Development

Ministry of Health of the Russian Federation

Instructions for Medical Use

Intesti®-Bacteriophage

Registration number: [Not provided]

Trade name: Intesti®-Bacteriophage

International non-proprietary or grouping name: Intesti-Bacteriophage

Dosage form: Solution for oral and rectal administration

Composition: In 1 ml of the preparation contains:

- Active substance: Sterile purified filtrates of phagolysates *S. flexneri* 1, 2, 3, 4 serotypes (with activity according to Appelman - not less than 10^6), *S. sonnei*, *S. typhimurium* (with activity according to Appelman - not less than 10^5), *S. flexneri* 6 serotype, other serotypes of *Salmonella*, *E. coli*, *Proteus*, *Enterococcus*, *Staphylococcus*, *P. aeruginosa* (with activity according to Appelman - not less than 10^4) - up to 1 ml.
- Excipients: Preservative - 8-hydroxyquinoline sulfate or 8-hydroxyquinoline sulfate monohydrate calculated as 8-hydroxyquinoline sulfate - 0.0001 g/ml (calculated content).

Description: Clear yellow liquid of varying intensity, a greenish tint is allowed.

Pharmacotherapeutic group: Not available.

ATX code: V03A.

Pharmacological properties: The preparation causes specific lysis of bacteria *Shigella flexneri* 1, 2, 3, 4, 6 serotypes, *Shigella sonnei*, *Salmonella paratyphi* A, *Salmonella paratyphi* B, *Salmonella typhimurium*, *Salmonella infantis*, *Salmonella choleraesuis*, *Salmonella oranienburg*, *Salmonella enteritidis*, enteropathogenic *Escherichia coli*, *Proteus vulgaris*, *Proteus mirabilis*, *Enterococcus*, *Staphylococcus*, *Pseudomonas aeruginosa*.

Indications for use:

- Treatment and prevention of gastrointestinal diseases caused by dysentery bacteria, salmonella, *Escherichia coli*, *Proteus*, *Enterococcus*, *Staphylococcus*, *Pseudomonas aeruginosa*, or their combination:
 - Bacterial dysentery
 - Salmonellosis
 - Dyspepsia

- Dysbacteriosis
- Enterocolitis, colitis

An important condition for effective phage therapy is the preliminary determination of the pathogen's phage sensitivity.

Contraindications: Hypersensitivity to the components of the preparation.

Use during pregnancy and lactation: Use of the preparation is advisable in the presence of infections caused by phage-sensitive strains of bacteria (as recommended by a doctor).

Method of administration and doses: The preparation is intended for oral and rectal administration. For treatment, take orally 4 times a day for 0.5 - 1 hour before meals from the first day of the disease for 7-10 days.

For infants in the first months of life, dilute the preparation with boiled water two times in the first two days of administration; in the absence of side effects (regurgitation, skin rashes), the bacteriophage can be used undiluted. Administer the preparation orally 3 times a day 30 minutes before feeding. In cases of persistent vomiting, the preparation is used in the form of high enemas (through a gas outlet tube or catheter) daily. It is possible to combine rectal (in the form of high enemas) and oral administration of the preparation. The course of treatment is 7-10 days.

Recommended dosages of the preparation:

Age	Dose per administration (ml)	
	Orally	Rectally
0 – 6 months	5	10
6 – 12 months	10	15
1 to 3 years	15	20
3 to 8 years	20	30
8 years and older	30	40

In the absence of colitic syndrome, it is recommended to replace one oral intake with a single rectal administration of the age-specific dose of the preparation in the form of an enema after bowel emptying.

For prophylactic purposes, the optimal scheme is the daily intake of the age-specific dose. The duration of the preparation intake is determined by the epidemic situation.

If there is no improvement after treatment or if symptoms worsen or new symptoms appear, consult a doctor. Use the preparation only according to the indications, the method of administration, and the doses indicated in the instructions.

Side effects: Possible allergic reactions. If you experience side effects listed in the instructions or they worsen, or if you notice any other side effects not listed in the instructions, inform your doctor.

Overdose: Cases of overdose have not been registered to date.

Interaction with other medicinal products: The use of the preparation is possible in combination with other medicinal products and does not preclude the use of other antibacterial agents.

Special instructions: An important condition for effective phage therapy is the preliminary determination of the pathogen's sensitivity to the bacteriophage and early use of the preparation.

Do not use the preparation in bottles with damaged integrity or labeling, expired, or cloudy.

Due to the content of the nutrient medium in the preparation, bacteria from the environment may develop, causing the preparation to become cloudy. It is necessary to observe the following rules when opening the bottle:

- Wash hands thoroughly;
- Treat the cap with an alcohol-containing solution;
- Remove the cap without opening the stopper;
- Do not place the stopper with the inner surface on the table or other objects;
- Do not leave the bottle open;
- Store the opened bottle only in the refrigerator.

Before use, shake the bottle with the bacteriophage and inspect it. The preparation should be clear and free of sediment. The opened bottle and extraction of the required volume of the preparation can be carried out with a sterile syringe by puncturing the stopper. The preparation from an opened bottle, when observing storage conditions, the above rules, and the absence of cloudiness, can be used throughout the shelf life.

Effect on the ability to drive vehicles and operate machinery: The preparation does not affect the ability to perform potentially dangerous activities that require increased concentration and speed of psychomotor reactions (including driving vehicles, working with moving mechanisms).

Form of release: Solution for oral and rectal administration. 20 or 100 ml in bottles. 4 or 10 bottles of 20 ml or 1 bottle of 100 ml in a carton pack with instructions for use.

Transportation conditions: At a temperature of 2 to 8 °C, transportation at a temperature of 9 to 25 °C is allowed for no more than 1 month.

Storage conditions: At a temperature of 2 to 8 °C in a dark place. Keep out of reach of children.

Shelf life: 2 years. Do not use after the expiration date.

Dispensing conditions: Over-the-counter.

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