Instructions for Medical Use of the Drug Infag®

Registration Number.

Trade Name. Infag®

International Nonproprietary or Group Name. Piobacteriophage.

Dosage Form. Solution for oral, topical, and external use.

Composition. 1 ml of the preparation contains:

Active Ingredient. Sterile purified filtrates of bacteriophages: Staphylococcus, Enterococcus, Streptococcus, Escherichia coli, Proteus vulgaris, Proteus mirabilis (activity according to Appelman - at least 10^-5), Pseudomonas aeruginosa, Klebsiella pneumoniae, Klebsiella oxytoca (activity according to Appelman - at least 10^-4) - up to 1 ml.

Excipients. 8-hydroxyquinoline sulfate/ 8-hydroxyquinoline sulfate monohydrate, recalculated as 8-hydroxyquinoline sulfate - 0.0001 g/ml (calculated content).

Description. Clear yellow liquid of varying intensity, possibly with a greenish tint.

Pharmacological Properties. Pharmacodynamic Properties. Pharmacotherapeutic Group: Other therapeutic agents.

ATC Code: V03AX.

Mechanism of Action. The preparation causes specific lysis of bacteria: Staphylococcus, Enterococcus, Streptococcus, Escherichia coli, Proteus vulgaris, Proteus mirabilis, Pseudomonas aeruginosa, Klebsiella pneumoniae, Klebsiella oxytoca.

Pharmacodynamic Effects. Studies on the pharmacodynamic properties of bacteriophages are not provided.

Pharmacokinetic Properties. Studies on the pharmacokinetic properties of bacteriophages are not provided.

Indications for Use.

Treatment and prevention of purulent-inflammatory and intestinal diseases caused by staphylococci, enterococci, streptococci, Pseudomonas aeruginosa, Klebsiella, pathogenic Escherichia coli of various serogroups, proteus with internal, rectal, and external use:

- diseases of the ear, throat, nose, respiratory tract, and lungs – inflammation of the sinuses, middle ear, angina, pharyngitis, laryngitis, tracheitis, bronchitis, pneumonia, pleurisy;
- surgical infections - wound suppurations, burns, abscesses, phlegmon, bursitis, carbuncles, hidradenitis, paronychia, paraproctitis, mastitis, bursitis, osteomyelitis;
- urogenital infections - urethritis, cystitis, pyelonephritis, colpitis, endometritis, salpingitis;

- post-traumatic conjunctivitis, keratoconjunctivitis, purulent corneal ulcers and iridocyclitis;
- enteric infections - gastroenterocolitis, cholecystitis, dysbiosis;
- generalized septic diseases;
- purulent-inflammatory diseases of newborns - omphalitis, pyoderma, conjunctivitis, gastroenterocolitis, sepsis, etc.;
- other diseases caused by bacteria: staphylococci, streptococci, enterococci, proteus, Klebsiella pneumoniae and oxytoca, Pseudomonas aeruginosa, and Escherichia coli. For prophylactic purposes, the preparation is used to treat surgical and fresh infected wounds, as well as for the prevention of nosocomial infections according to epidemiological indications.

Contraindications. Hypersensitivity to the components of the preparation.

Pregnancy, Breastfeeding, and Fertility.

Pregnancy. The use of this preparation during pregnancy is considered advisable.

Breastfeeding. The use of this preparation during breastfeeding is considered advisable.

Fertility. No data on the effects of the medicinal product on human fertility.

Method of Administration and Dosage.

Method of Administration. The treatment of purulent-inflammatory diseases with localized lesions should be carried out both locally and orally simultaneously for 7-20 days (according to clinical indications).

Dosage Regimen.

Depending on the nature of the infection focus, the bacteriophage is used as follows:

1. Locally in the form of irrigation, lotions, and tampons with liquid phage in quantities up to 200 ml, depending on the size of the affected area. In the case of abscesses, the bacteriophage is introduced into the cavity of the focus after removing the pus with a puncture. The amount of the introduced preparation should be slightly less than the volume of the removed pus. In osteomyelitis, after appropriate surgical treatment, 10-20 ml of the bacteriophage is poured into the wound.
2. In cavities - pleural, joint, and other limited cavities up to 100 ml of bacteriophage, after which a capillary drainage is left, through which the bacteriophage is reintroduced over several days.
3. For cystitis, pyelonephritis, urethritis, the preparation is used orally. In cases where the bladder or renal pelvis is drained, the bacteriophage is introduced through a cystostomy or nephrostomy 1-2 times a day in 20-50 ml into the bladder and 5-7 ml into the renal pelvis.
4. For purulent-inflammatory gynecological diseases, the preparation is introduced into the vaginal cavity, uterus at a dose of 5-10 ml daily once.
5. For purulent-inflammatory diseases of the ear, throat, nose, the preparation is used in a dose of 2-10 ml 1-3 times a day. The bacteriophage is used for rinsing, washing, instilling, and introducing wet turundas (leaving them for 1 hour).
6. For conjunctivitis and keratoconjunctivitis, the preparation is instilled 2-3 drops 4-5 times a day, for purulent corneal ulcers - 4-5 drops, for purulent iridocyclitis, the preparation is used 6-8 drops every 3 hours in combination with oral administration.

7. For the treatment of stomatitis and chronic generalized periodontitis, the preparation is used as a mouth rinse 3-4 times a day at a dose of 10-20 ml, as well as by introducing turundas soaked in piobacteriophage into periodontal pockets for 5-10 minutes.
8. For intestinal forms of diseases, diseases of internal organs, dysbiosis, the bacteriophage is used orally and rectally. Orally, the bacteriophage is given 3 times a day on an empty stomach 1 hour before meals. Rectally, it is administered 1 time a day instead of one oral administration.

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

Recommended dosages of the preparation: The use of bacteriophages does not exclude the use of other antibacterial drugs. If chemical antiseptics were used to treat wounds before the use of the bacteriophage, the wound should be thoroughly rinsed with sterile 0.9% sodium chloride solution.

Special Groups of Patients.

Elderly Patients: No special dosage recommendations.

Patients with Renal Dysfunction: No special dosage recommendations.

Patients with Hepatic Dysfunction: No special dosage recommendations.

Children.

Children (up to 6 months). In sepsis, enterocolitis of newborns, including premature babies, the bacteriophage is used in the form of high enemas (through a gas tube or catheter) 2-3 times a day. In the absence of vomiting and regurgitation, it is possible to use the preparation orally. In this case, it is mixed with breast milk. Combined rectal (in enemas) and oral (orally) use of the preparation is possible. The course of treatment is 5-15 days. With recurrent disease, repeated treatment courses are possible. For

prophylaxis of sepsis and enterocolitis in hospital infections in newborns, the bacteriophage is used in enemas 2 times a day for 5-7 days. In the treatment of omphalitis, pyoderma, infected wounds, the preparation is used as applications daily twice (a gauze napkin soaked in the bacteriophage is applied to the navel wound or the affected area of the skin).

Children. The preparation can be used in children at doses specified in the "Dosage Regimen" section. If there is no improvement after treatment, or symptoms worsen, or new symptoms appear, consult a doctor. Use the preparation only according to the indications, method of use, and in doses specified in the instructions.

Side Effects. Possible allergic reactions.

Side effects mentioned in the instructions, or they worsen, or you notice any other side effects not mentioned in the instructions, inform your doctor.

Overdose. No cases of overdose have been reported to date.

Interaction with Other Medicinal Products. The use of the preparation is possible in combination with other medicinal products, including antibiotics.

Special Instructions. An important condition for effective phage therapy is the preliminary determination of the sensitivity of pathogens to the bacteriophage and the early use of the preparation. The preparation is not suitable for use in vials with a damaged integrity or labeling, after the expiration date, or when cloudy. Due to the content of nutrient medium in the preparation, in which bacteria from the environment can develop, causing cloudiness of the preparation, it is necessary to follow these rules when opening the vial:

- wash hands thoroughly;
- treat the cap with an alcohol-containing solution;
- remove the cap without opening the stopper;
- do not place the stopper with its inner surface on the table or other objects;
- do not leave the vial open;
- store the opened vial only in the refrigerator. Before use, shake the vial with the bacteriophage and inspect it. The preparation should be clear. Opening the vial and extracting the required volume of the preparation can be done with a sterile syringe by piercing the stopper. The preparation from an opened vial, if stored properly, and the listed rules and the absence of cloudiness are observed, can be used throughout the entire shelf life.

Effects on the Ability to Drive Vehicles and Operate Machinery. The preparation does not affect the ability to perform potentially hazardous activities that require increased concentration and speed of psychomotor reactions (including driving vehicles, working with moving mechanisms).

Release Form. Solution for oral, topical, and external use. In 20 ml or 100 ml vials. 8 vials of 20 ml or 1 vial of 100 ml in a cardboard package together 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 place protected from light. Keep out of the reach of children.

Shelf Life. 2 years. Do not use after the expiration date.

Dispensing Conditions. Dispensed without a prescription.

Registration Certificate Holder. AO "NPO "Microgen". Russia, 115088, Moscow, 1st Dubrovskaya St., 15, bldg. 2.

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