MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

INSTRUCTION FOR MEDICAL USE

MEDICINAL PRODUCT

"Sextaphage®" Piobacteriophage polyvalent

Registration number.

Trade name. "Sextaphage®" Piobacteriophage polyvalent.

International non-proprietary or grouping name.

Piobacteriophage.

Dosage form: solution for oral, local, and external use.

Composition.

In 1 ml of the preparation contains:

Active substance.

Sterile purified filtrates of phagolysates of bacteria Staphylococcus spp., Streptococcus spp., Proteus (P. vulgaris, P. mirabilis), Pseudomonas aeruginosa, Klebsiella pneumoniae, enteropathogenic Escherichia coli (with Appelman's activity - at least 10-5) – up to 1 ml.

Excipient.

8-hydroxyquinoline sulfate monohydrate (preservative) calculated as 8-hydroxyquinoline sulfate - 0.0001 g/ml (calculated content).

Description. Transparent yellow liquid of varying intensity, a greenish tint is possible.

Pharmacotherapeutic group. Absent.

ATX code. V03A.

Pharmacological properties. The drug has the ability to specifically lyse bacteria of staphylococci, streptococci (including enterococci), Proteus, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Escherichia coli.

Indications for use: treatment and prevention of purulent-inflammatory and enteral diseases caused by staphylococci, streptococci, Proteus, Klebsiella, Pseudomonas aeruginosa, and Escherichia coli:

- Diseases of the ear, throat, nose, respiratory tract, and lungs - inflammation of the sinuses, middle ear, tonsillitis, pharyngitis, laryngitis, tracheitis, bronchitis, pneumonia, pleurisy;
- Surgical infections - wound suppuration, burns, abscesses, phlegmons, boils, carbuncles, hidradenitis, panaritium, paraproctitis, mastitis, bursitis, osteomyelitis;
- Urogenital infections - urethritis, cystitis, pyelonephritis, colpitis, endometritis, salpingo-oophoritis;
- Post-traumatic conjunctivitis, keratoconjunctivitis, purulent corneal ulcers, and iridocyclitis;
- Enteral infections - gastroenterocolitis, cholecystitis, dysbacteriosis;
- Generalized septic diseases;
- Purulent-inflammatory diseases of newborns - omphalitis, pyoderma, conjunctivitis, gastroenterocolitis, sepsis, etc.;
- Other diseases caused by staphylococci, streptococci (including enterococci), Proteus, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Escherichia coli.

In severe infections caused by staphylococci, streptococci, Proteus, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Escherichia coli, the drug is prescribed as part of combination therapy.

For prophylactic purposes, the drug is used to treat surgical and freshly infected wounds, as well as for the prevention of nosocomial infections according to epidemic indications.

An important condition for effective phagotherapy is the preliminary determination of the sensitivity of the pathogen to the bacteriophage.

Contraindications. Absent.

Use during pregnancy and lactation. The use of the drug during pregnancy and lactation is advisable in the presence of infections caused by phage-sensitive bacterial strains (as recommended by a doctor).

Method of administration and doses. Before use, shake the vial with the bacteriophage and inspect. The preparation should be transparent and free of sediment.

Treatment of purulent-inflammatory diseases with localized lesions should be carried out both locally and by taking the drug orally for 7-20 days (according to clinical indications).

Depending on the nature of the infection site, the bacteriophage is used:

1. Locally in the form of irrigation, lotions, and tamponades with liquid phage in quantities up to 200 ml depending on the size of the affected area. In abscesses, the bacteriophage is introduced into the cavity of the focus after removing the pus by puncture. The amount of drug injected should be slightly less than the volume of the

removed pus. In osteomyelitis, after appropriate surgical treatment, bacteriophage is poured into the wound 10-20 ml.

2. Introduction into 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 re-introduced for several days.
3. For cystitis, pyelonephritis, urethritis, the drug is taken orally. If the bladder or renal pelvis is drained, the bacteriophage is administered through a cystostomy or nephrostomy 1-2 times a day, 20-50 ml into the bladder and 5-7 ml into the renal pelvis.
4. In gynecological purulent-inflammatory diseases, the drug is administered into the vagina or uterus in a dose of 5-10 ml daily once.
5. In purulent-inflammatory diseases of the ear, throat, nose, the drug is administered in a dose of 2-10 ml 1-3 times a day. The bacteriophage is used for rinsing, washing, instillation, and introduction of moistened turunds (leaving them for 1 hour).
6. In conjunctivitis and keratoconjunctivitis, the drug is instilled 2-3 drops 4-5 times a day, in purulent corneal ulcers - 4-5 drops, in purulent iridocyclitis - 6-8 drops every 3 hours in combination with oral administration.
7. In the treatment of stomatitis and chronic generalized periodontitis, the drug is used in the form of mouth rinses 3-4 times a day in a dose of 10-20 ml, and also by introducing turunds soaked in piobacteriophage into periodontal pockets for 5-10 minutes.
8. In intestinal forms of the disease, internal organs diseases, dysbacteriosis, the bacteriophage is used orally and in the form of enemas for 7-20 days. Orally, the bacteriophage is given 3 times a day on an empty stomach 1 hour before meals. In the form of enemas, it is administered once a day instead of one oral intake.

Recommended dosages of the drug

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

If chemical antiseptics were used to treat wounds before using the bacteriophage, the wound should be thoroughly washed with sterile 0.9% sodium chloride solution.

Use of bacteriophage in children (up to 6 months). In sepsis, enterocolitis of newborns, including premature babies, the bacteriophage is used in high enemas (through a gas

tube or catheter) 2-3 times a day (see table). In the absence of vomiting and regurgitation, oral administration of the drug is possible. In this case, it is mixed with breast milk. It is possible to combine rectal (in enemas) and oral administration of the drug. The course of treatment is 5-15 days. In recurrent disease, repeated courses of treatment are possible. For the prevention of sepsis and enterocolitis in intrauterine infection or the risk of nosocomial infection 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 drug is used in the form of applications twice a day (a gauze napkin soaked in bacteriophage is applied to the umbilical wound or affected area of the skin).

If no improvement is observed after treatment or symptoms worsen, or new symptoms appear, consult a doctor. Use the drug only according to the indications, the method of application, and the doses specified in the instructions.

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

Overdose. Cases of overdose have not been registered so far.

Interaction with other medicinal products. The use of the drug is possible in combination with other medicinal products, including antibiotics.

Special instructions. An important condition for effective phagotherapy is the preliminary determination of the sensitivity of the pathogen to the bacteriophage and the early use of the drug.

The drug is not suitable for use in vials with damaged integrity or labeling, after the expiration date, and in case of clouding.

Before use, shake the vial with the liquid bacteriophage. Do not use the drug if it is cloudy!

Due to the content of a nutrient medium in the preparation, which may allow bacteria from the environment to develop and cause clouding of the preparation, the following rules must be observed when opening the vial:

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

When using small doses (2-8 drops), the drug should be taken with a sterile syringe in a volume of 0.5-1 ml.

The drug from the opened vial, subject to storage conditions, the above rules, and the absence of clouding, can be used throughout the shelf life.

Influence on the ability to drive vehicles and mechanisms. The drug does not affect the ability to perform potentially dangerous activities requiring increased concentration and speed of psychomotor reactions (including driving vehicles, working with moving mechanisms).

Release form. Solution for oral, local, and external use.

20 ml in glass vials.

A. 4 or 10 vials of 20 ml in a cardboard box with instructions for use.

B. 4 vials of 20 ml in a fixing insert made of polymer materials. 1 fixing insert made of polymer materials in a cardboard box with instructions for use.

Transport conditions. At temperatures from 2 to 8 °C, transport is allowed at temperatures from 9 to 25 °C for no more than 1 month.

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

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

Dispensing conditions. Available without a prescription.

Registration certificate holder.

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Manufacturer.

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Organization accepting consumer claims.

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