

## **Pyophage® - Patient leaflet (Instruction for medical use)**

The product contains bacteriophages specifically eliminating such causative agents of pyoinflammatory and enteric diseases as:

Streptococcus pyogenes  
Staphylococcus aureus  
Escherichia coli  
Pseudomonas aeruginosa  
Proteus vulgaris  
Proteus mirabilis

The bacteriophages contained in the product proliferate inside the bacterial cells and destroy them. The bacteriophages also induce activation of immune reactions in the body, preventing recurrence of infectious disease and transition of the inflammatory process into a chronic form.

The product does not violate the condition of the normal microflora in the gastro-intestinal tract.

### **Pyophage®**

The full information on the product is given in the instruction for medical use. Before use read the Instructions for medical use of Pyophage® medicinal product.

### **Indications for use of Pyophage® medicinal product**

- Pyoinflammatory diseases of ears (otitis), throat (pharyngitis, laryngitis, angina), nose (sinusitis);
- Pyoinflammatory diseases of oral cavity (stomatitis, gingivitis, periodontitis);
- Pyoinflammatory diseases of eyes (conjunctivitis, keratoconjunctivitis, etc.);
- Surgical infections (treatment of surgical and sordid wounds, abscesses, phlegmons, furuncles, carbuncles, etc.);
- Burn wounds;
- Urogenital infections (cystitis, urethritis, colpitis, pyelonephritis, etc.);
- Pyoinflammatory gynaecologic diseases;
- Enteric infections;
- Dysbacteriosis.

### **Drug form**

Solution in vial.

### **Administration of Pyophage® medicinal product**

The treatment of pyoinflammatory diseases with a localized size of disease is carried out locally as well as orally.

In case of pyoinflammatory diseases of ear, throat, and nose the product is applied in the dosage of 2-10 ml 1-3 times a day in the form of washes, rinsing, dripping, insertion of soaked cotton turundas (left inside for 1:00 hour).

In treatment of stomatitis and periodontitis the product is used in the form of oral cavity washes 3-4 times a day in the dosage of 10-20 ml, as well as installing the turundas soaked in the product in the periodontal pockets for 5-10 minutes.

In case of conjunctivitis and keratoconjunctivitis the product is instilled in the eye 4-5 times a day 2-3 drops in one eye. In case of application of little doses the product should be taken from the vial with a sterile syringe of 0.5-1 ml.

In case of surgical infections and burns the product is applied in the form of irrigations, packs, and tamponing with liquid phage in the amount up to 200 ml depending on the size of the affected area. If before using of the bacteriophages the wound was treated with chemical antiseptics it has to be thoroughly washed with a sterile saline solution.

In case of enteric infections and dysbacteriosis the product is applied orally and in enemas. The bacteriophage is applied orally 3 times a day (fasting 1:00 hour before meals). Rectally (in enemas) the product is administered 1 time a day after defecation instead of 1 oral administration.

The duration of treatment is 7-10 days.

#### **Dosage**

The dosage of product depends on the age of the patient and the way of administration.

<b>Age</b>	<b>Dosage per 1 administration (ml)</b>	
	<b>orally</b>	<b>rectally (enemas)</b>
from 2 to 6 month	5	10
from 6 to 12 month	10	20
from 1 to 3 years	15	30
from 3 to 8 years	20	40
8 years and older	30	50

**As a preventive measure** bacteriophage is administered orally according to the age dose 1 time a day 1 hour before meals. The duration of the course depends on the epidemic situation.

#### **Side effects of Pyophage® medicinal product**

No cases of adverse reactions were described.

#### **Contraindications to administration of Pyophage® medicinal product**

Hypersensitisation to the product components.

#### **Administration of Pyophage® medicinal product during pregnancy and breastfeeding period**

The safety and efficiency of the product during pregnancy and breastfeeding period is not yet ascertained, therefore it is advisable to consult your physician before use.

**Drug-to-drug interaction**

The product can be used along with the other antibacterial agents.

**Administration details of Pyophage® medicinal product**

The essential condition for an efficient phagotherapy is a prior definition of the causative bacterium phagosensitivity. The product should be administered as soon as possible.

If you use only a part of the solution from the vial per administration, the following rules should be observed:

- thoroughly wash your hands before opening the vial,
- take off the cap without removing the stopper,
- withdraw the solution from the vial only using a sterile syringe by the way of puncturing the stopper,
- don't leave the vial opened, keep in the fridge.

**Caution**

The information on the product is presented for information purposes only and shall not be used as a guide for self-treatment. Only a doctor can make a decision as to prescribing of the product, as well as doses thereof and method of administration.

**Manufacturer**

Pyophage® medicinal product is manufactured by "PHARMEX GROUP" LLC, Ukraine, for NeoProbioCare Inc., Canada.