

**MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION**

**INSTRUCTION**

**FOR MEDICAL USE OF MEDICATION**

**Miramistin®**

*Read this instruction carefully before using this medication because the instruction contains the information which is important for you.*

*Keep the instruction as you may need it in the future.*

*In case of any questions, consult a doctor.*

*The medicine you are using was prescribed specifically to you and should not be passed to any other persons because it might harm them even if they have the same symptoms as you.*

**Registration number:** P N001926/01

**Trade name:** Miramistin®

**International nonproprietary or generic name:** Benzyl dimethyl-myristoyl amine-propyl ammonium

**Medicinal form:** Topical solution

**Composition:**

*Composition per 1 l:*

*Active substance:* benzyl dimethyl[3-(myristoylamine)-propyl] ammonium chloride monohydrate (on an anhydrous substance basis) – 0.1 g

*Excipient:* purified water – ad 1 l

**Description:** colorless transparent liquid forming foam when shaken

**Therapeutic category:** antiseptic medicine

**ATX code:** D08AJ

**Pharmacological properties**

*Pharmacodynamics*

Miramistin has a wide antimicrobial effect, including hospital strains resistant to

antibiotics.

The medicine has a significant antimicrobial effect against gram-positive (*Staphylococcus spp.*, *Streptococcus spp.*, *Streptococcus pneumoniae*) and gram-negative (*Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella spp.*), aerobic and anaerobic bacteria in the form of one-species cultures and microbial associations, including polyresistant hospital strains.

It has an antifungal effect on ascomycetes of *Aspergillus* and *Penicillium* genera, yeasts (*Rhodotorula rubra*, *Torulopsis glabrata*) and yeast-like fungi (*Candida albicans*, *Candida tropicalis*, *Candida krusei*, *Pityrosporum orbiculare* (*Malassezia furfur*), dermatophytes (*Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Trichophyton verrucosum*, *Trichophyton schoenleini*, *Trichophyton violaceum*, *Epidermophyton Kaufman-Wolf*, *Epidermophyton floccosum*, *Microsporum gypseum*, *Microsporum canis*) in the form of one-species cultures and microbial associations, including fungous microflora resistant to chemotherapeutic compounds.

It produces an antiviral action and is active against complex viruses (herpes, human immunodeficiency viruses).

Miramistin<sup>®</sup> is active against sexually transmitted pathogens (*Chlamydia spp.*, *Treponema spp.*, *Trichomonas vaginalis*, *Neisseria gonorrhoeae*).

It effectively prevents the ingress of infection to wounds and burns and activates regenerative processes. It stimulates defensive reactions in the place of administration and intensifies the activity of monocyte-macrophagal system by activating the absorption and digestion functions of phagocytes. Miramistin is characterized by a significant hyperosmolar activity, which is why it stops the wound and perifocal inflammation and absorbs purulent effluent contributing to the formation of a dry scab. It does not damage granulation tissues and vital skin cells and does not suppress marginal epithelialization.

It has no local irritant effect or allergizing properties.

### ***Pharmacokinetics***

When applied locally, Miramistin® cannot be absorbed through the skin and mucous membranes.

### **Indications for use**

Otorhinolaryngology: complex treatment of acute and chronic external otitis, highmoritis, tonsillitis, pharyngitis, laryngitis.

Odontology: treatment and prevention of inflammatory infection of the mouth cavity: stomatitis, gingivitis, parodontitis, periodontitis. Cleaning of removable dentures.

Surgery, traumatology: prevention of suppuration and suppurative wound treatment. Treatment of pyoinflammatory processes in the locomotor system.

Obstetrics and gynecology: prevention and treatment of puerperal trauma suppuration, perineal and vaginal wounds, obstetric infections, inflammatory diseases (vulvovaginitis).

Combustiology: treatment of superficial scalds and deep burns of II and IIIA degrees, preparation of burn wounds for dermoplasty.

Dermatology: treatment and prevention of pyodermia and dermatomycosis, foot mycosis, cutaneous and mucous candidosis.

Venereology: individual preventive treatment of sexually transmitted diseases (syphilis, gonorrhea, chlamidiosis, trichomoniasis, genital herpes, genital moniliasis).

Urology: complex treatment of acute and chronic urethritis and urethroprostatitis of specific (chlamidiosis, trichomoniasis, gonorrhea) and non-specific nature.

### **Contraindications**

Hypersensitivity to the active substance.

Using the medicine in the form of spray to irrigate the throat and tonsils for children under the age of 3 is not recommended due to the risk of reactive laryngospasm.

## **Administration during pregnancy and breast-feeding period**

According to the available data, the medicine can be used during pregnancy and breast-feeding period because the medicine produces no systemic effect when administered in compliance with the instruction but its use is left to the discretion of the doctor.

## **Method of administration and dosage**

The medicine is ready for application.

*Indications for the use of packaging with a spray nozzle:*

1. Remove the cap from the bottle, also remove the urologic applicator from the 50 ml bottle.
2. Take out the enclosed spray nozzle from the protective packaging.
3. Attach the spray nozzle to the bottle.
4. Activate the spray nozzle by repeated pressing.

*Indications for the use of 50 ml or 100 ml packaging with a gynecologic nozzle:*

1. Remove the cap from the bottle.
2. Take out the enclosed gynecologic nozzle from the protective packaging.
3. Attach the gynecologic nozzle to the bottle without removing the urologic applicator.

*Indications for the use of 100 ml, 150 ml, 200 ml packaging with a dosing cup:*

To use the medicine for gargling, dose the amount of medicine needed for one gargling using the enclosed dosing cup.

## **Otorhinolaryngology**

### ***Adults and children***

*In case of maxillary sinusitis*, flush the maxillary antrum with a sufficient amount of Miramistin® during the puncture.

*Acute and chronic external otitis*: instill up to 5 drops of the medicine in the external auditory canal 4 times a day using a dropping pipette or, instead of

instillation, place a gauze drain impregnated with the medicine in the external auditory canal 4 times a day. The period of treatment is 10 days.

*Tonsillitis, pharyngitis, and laryngitis:*

**Children of 3-6:** press the head of the spray nozzle once or use 3-5 ml of the medicine per one gargling 3-4 times a day;

**Children of 7-14:** press the head of the spray nozzle two times or use 5-7 ml of the medicine per one gargling 3-4 times a day;

**Children over 14 and adults:** Press the head of the spray nozzle 3-4 times or use 10-15 ml of the medicine per one gargling 3-4 times a day.

The period of treatment varies from 4 to 10 days depending on the start of remission.

### **Odontology**

#### ***Adults and children***

In case of stomatitis, gingivitis, parodontitis, mouth wash is recommended using 10-15 ml of the drug 3-4 times a day. If gargling is not possible, gauze or cotton wool tampons wetted with Miramistin® solution can be used topically.

### **Surgery, traumatology, combustiology**

#### ***Adults and children***

For the purpose of treatment and prevention of repeated introduction of infection in wounds, irrigate the surface of wounds with Miramistin solution®.

Attach gauze tampons impregnated with Miramistin® solution on the wound surface.

Tampons can be inserted in wounds and/or fistulous passages during surgical manipulations, as necessary.

Active draining of wounds and/or cavities is possible. The daily flow of Miramistin® is up to 1 l per day.

### **Obstetrics, gynecology**

#### ***Adults***

*Prevention and treatment of puerperal trauma suppuration, perineal and vaginal wounds, obstetric infections:* Use Miramistin® in the form of vaginal irrigation prior to the delivery (for 5-7 days), during the delivery after every examination. In the postpartum period, Miramistin® is used in the form of tampons wetted with 50 ml of the medicine applied for 2 hours for 5 days.

In case of operative delivery by means of C-section, treat the vagina immediately before the operation, apply the medicine on the uterine cavity and the uterine incision during the operation, and during the postoperative period insert tampons impregnated with Miramistin® in the vagina for 2 hours for 7 days.

Inflammatory diseases are treated in the form of a course of medication during 2 weeks by inserting tampons impregnated with Miramistin® in the vagina or by medical ionization.

*Complex treatment of inflammatory conditions in gynecology (vulvovaginitis):* Perform vaginal irrigation or insert tampons wetted with Miramistin® for 2 hours for 7-14 days (the duration of treatment and frequency of administration are to be defined by medical prescription).

For convenience, use the gynecologic nozzle for vaginal irrigations. Use the gynecologic nozzle to introduce the contents of the bottle in the vagina and perform irrigation.

### ***Children***

The application method, duration of treatment and frequency of administration are to be defined by medical prescription.

### **Dermatology**

#### ***Adults and children***

*Treatment and prevention of pyodermia and dermatomycosis, cutaneous and mucous candidosis, foot mycosis:* apply Miramistin® to the affected skin area by cleaning it with sterile gauze sponges amply wetted with the medicine. Miramistin® is used 3 times a day on the affected skin areas.

## **Venereology**

### ***Adults***

*Prevention of sexually transmitted diseases:* Miramistin® is effective if applied within 2 hours after the sexual intercourse.

Use the applicator to introduce the contents of the bottle into the urinary tract for 2-3 minutes:

Men: 2-3 ml of the medicine;

Women: Introduce 1-2 ml of the medicine into the urinary tract and 5-10 ml in the vagina (for convenience, use the gynecologic nozzle).

Cleanse the skin of the inner side of thighs, pubis, genitals.

Abstain from urination for 2 hours after the procedure.

## **Urology**

### ***Adults***

As part of complex treatment of urethritis and urethroprostatitis, inject 2-3 ml of Miramistin® in the urethra 1-2 times a day for 10 days.

### ***Children***

The application method, duration of treatment and frequency of administration are to be defined by medical prescription.

*If the treatment produces no positive effect or the symptoms become more intense, or new symptoms appear, consult the doctor. Use the medicine only according to the administration method and in the doses specified in the Instruction.*

### **Side effects**

The rate of occurrence of adverse reactions is defined in the following way: very common ( $\geq 1/10$ ); common ( $\geq 1/100$  but  $< 1/10$ ); uncommon ( $\geq 1/1000$  but  $< 1/100$ ); rare ( $\geq 1/10000$  but  $< 1/1000$ ); very rare ( $< 1/10000$ ); occurrence is not known (cannot be assessed based on the available data).

Very rare (<1/10000):

- slight burning that disappears on its own in 15-20 seconds and does not require the medicine withdrawal;
- allergic reactions.

*If you have any side effects described in the Instruction of Medical Use or they become more intense, or you have noticed any other effects not described in the Instruction, inform the doctor.*

### **Overdosage**

No overdose events involving topical or external application of the medicine were registered.

### **Drug-to-drug interaction**

When used together with antibiotics, the medicine enhances their antibacterial and antifungal properties.

### **Special warnings**

Using the same bottle by more than one person may cause the infection spread.

### **Presentation**

0.01 % topical solution.

50 ml, 100 ml polyethylene bottles with an urological applicator with a screw-on cap

50 ml polyethylene bottles with an urological applicator with a screw-on cap complete with a spray cap.

50 ml, 100 ml polyethylene bottles with an urological applicator with a screw-on cap complete with a gynecologic nozzle.

50 ml, 100 ml, 150 ml, 200 ml polyethylene bottles supplied with a spray cap or complete with a spray pump and protection cap.

100 ml, 150 ml, 200 ml polyethylene bottles supplied with a spray cap or complete

with a spray pump and protection cap, with a polyethylene dosing cup.

500 ml polyethylene bottles with a tamper proof screw-on cap.

Each 50 ml, 100 ml, 150 ml, 200 ml, 500 ml bottle is placed in a cardboard carton together with the instruction for use.

For in-patient hospitals: 12 500 ml bottles without cartons are placed in a cardboard box made of folding-box carton together with the same number of instructions for use.

### **Storage conditions**

Do not store at a temperature above 25 °C.

Keep out of the reach of children.

### **Shelf life**

3 years. Do not use upon expiration of the shelf life.

### **Prescription status**

Over the counter.

### **Manufactured by:**

INFAMED K LLC,

12, Kommunalnaya St., Bagrationovsk, Bagrationovsky District, Kaliningrad Region, Russia, 238420

Tel.: (4012) 31-03-66

### **Organization authorized to accept customer complaints**

INFAMED LLC

Office 9, 2nd floor, bldg. 473, territory of VZ GIAP JSC industrial zone, Vidnoe, Leninsky District, Moscow Region, Russia, 142700

Tel.: 8 (800) 700-48-12; e-mail: [infamed@infamed.ru](mailto:infamed@infamed.ru); website:

[www.miramistin.ru](http://www.miramistin.ru)

General Director

I. G. Khugaeva