

## PRODUCT LABEL

### Instruction for medical use of antiseptic drug

#### Miramistin®

**Registration number:** P N001926/01

**Trade name:** Miramistin®

**Chemical name:**

benzyltrimethyl[3-(myristoylamino)propyl]ammonium chloride monohydrate

**Drug form:** Solution for local administration

**Description:**

*Active substance:* benzyltrimethyl[3-(myristoylamino)propyl]ammonium chloride monohydrate (miramistin, as an anhydrous agent) – 0.01g

*Ancillary substance:* purified water – up to 1 l

**Description:** colourless, transparent liquid, making foam when shaken.

**Pharmacological group:** Antiseptic drug.

**Anatomical Therapeutic Chemical Classification System Code:**

[D08AJ]

### CLINICAL PHARMACOLOGY

Miramistin® exerts a profound antibacterial effect, including to hospital strains with resistance to antibiotics.

Miramistin® is the most efficient to combat gram-positive bacteria (*Staphylococcus spp.*, *Streptococcus spp.*, *Streptococcus pneumoniae*, etc.), gram-negative (*Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella spp.*, etc.), aerobic and anaerobic bacteria in the form of monocultures and microbe associations, including hospital strains with multiresistance to antibiotics.

Miramistin® exerts anti-mycotic effect on *Aspergillus* and *Penicillium*, saccharomyces (*Rhodotorula rubra*, *Torulopsis gabrata*, etc.) and saccharomyce-like ones (*Candida albicans*, *Candida tropicalis*, *Candida krusei*, *Pityrosporum orbiculare* (*Malassezia furfur*) etc.), dermatophytes (*Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Trichophyton verrucosum*, *Trichophyton schoenleini*, *Trichophyton violaceum*, *Epidermophyton Kaufman-Wolf*, *Epidermophyton floccosum*, *Microsporum gypseum*, *Microsporum canis*, etc.), and any other pathogenic fungi, in the form of monocultures and microbe association, including one of the fungous microflora characterized by its resistance to chemotherapy medications.

Miramistin® exerts antiviral action, is active with respect to complex viruses (herpes,

human immunodeficiency virus, etc.).

Miramistin® suppress microbes causing sexually transmitted infections (Chlamydia spp., Treponema spp., Trichomonas vaginalis, Neisseria gonorrhoeae, etc.).

Miramistin® effectively prevents contamination of wounds and burns. It stimulates regeneration processes. It stimulates protective responses at the administration sites through stimulation of phagocyte function to engulf and digest and potentiates the activity of monocytic macrophage system. It exerts vigorous hyperosmolar action which allows for substantial reduction of wound and perifocal inflammation, absorbs purulent exudate, enabling dry crust formation. It does not destroy granulation and viable skin cells; does not oppress edge epithelialization.

It does not exhibit local irritation and allergic properties.

### **Pharmacokinetics**

Following local administration, miramistin is not absorbed through skin and mucosa.

### **Indications**

Surgery and traumatic surgery: prevention of suppuration and treatment for festering wounds, as well as suppurative inflammation processes in locomotor apparatus.

Obstetrics and gynecology: Prevention and treatment of suppurative post-natal injuries, perineum and vaginal wounds, post-natal infections, inflammatory diseases (vulvovaginitis and endometritis).

Kombustology: treatment for minor and serious burns of the second and third degrees, preparation of burns for dermatoplasty.

Dermatology and venereology: Prevention and treatment of pyoderma and dermatomycosis, skin and mucous membrane candidasies, sole mycosis.

Individual preventive care of sexually transmitted infections (syphilis, gonorrhea, clamidiosis, trichomoniasis, genital herpes, genital candidiasis, etc.).

Urology: complex treatment for acute and chronic urethritis and urethroprostatitis of general and specific (chlamydosis, trichomoniasis, gonorrhoea) and nonspecific kinds.

Stomatology: Prevention and treatment of infectious and inflammatory diseases of mouth cavity: stomatitis, gingivitis, paracementitis and pericementitis. Hygienic treatment of separable dentures.

Otolaryngology: complex treatment of acute and chronic otitis, antritis, tonsillitis, laryngitis, and pharyngitis.

Pediatric Use: Miramistin® is used in 3-14 years old patients for complex treatment of acute pharyngitis and/or chronic tonsillitis relapse.

### **Contraindications**

Idiosyncrasy to the drug.

### Dosage and Administration

Ready to use

Indications for use the vial with a spray nozzle:

1. Remove the cap of the vial, remove the urologic applicator of the vial 50 ml.
2. Remove the spray nozzle from the protective packaging.
3. Attach the spray nozzle to the vial.
4. Activate the spray nozzle by double press.

Indications for use the vial 50 ml or 100 ml with a gynecological nozzle:

1. Remove the cap of the vial.
2. Remove the gynecological nozzle from the protective packaging.
3. Attach gynecological nozzle to the vial without removing the urologic applicator.

### Surgery, traumatic surgery, and kombustology:

For prophylactic and treatment purposes, irrigate wounds and burns surfaces, apply loose pack to wounds and fistulous tracts, fix gauze plug moistened with Miramistin. Repeat 2-3 times a day during 3-5 days. Wounds and cavities active drainage with daily flow of Miramistin up to 1L is highly effective.

### Obstetrics and gynecology

To prevent post-natal infections, irrigate vagina prior to delivery (5-7 days), apply 50 ml of Miramistin as a tampon (exposure time 2 hours) during delivery after each vaginal touch and during puerperal period for 5 days. In case of Caesarian operation, irrigate vagina just before the operation, during the operation – irrigate uterine cavity and the section, in post operation period - insert a tampon moistened with the drug into vagina, with exposure time 2 hours for 7 days. Inflammatory disease treatment is carried out as 2 weeks courses and include intravaginal introduction of tampon moistened with Miramistin and ionic medication.

### Venereology

Miramistin is effective in prevention of venereal disease if used within 2 hours after sexual intercourse. Using urological applicator, introduce the solution into urethra for 2-3 minutes: for men (2-3ml), for women (1-2ml) and into vagina (5-10ml). Treat the inner surface of hip, pubis and genital organs. It is recommended not to micturate for 2 hours after application of the drug.

### Urology

Within the complex treatment of urethritis and urethroprostatitis, inject 2-3 ml of Miramistin into urethra 1-2 times daily for 10 days.

### Otolaryngology

In case of purulent genyantritis, irrigate genyantrum with sufficient volume of Miramistin during the centesis.

Tonsillitis, pharyngitis and laryngitis are treated by gargling and/or irrigation using a spray nozzle by pressing 3-4 each time 3-4 times per day. Use 10-15ml for one gargle.

### Pediatric Use

In case of acute pharyngitis and/or chronic tonsillitis relapse, irrigate the throat using spray nozzle. In 3-6 years old children: Press on the top of the spray nozzle (3-5ml for

one irrigation), 3-4 times per day; in 7-14 years old children: press twice (5-7ml for one irrigation), 3-4 times per day; in children above 14 press 3-4 times (10-15ml for one irrigation), 3-4 times per day. The treatment duration should be from 4 to 10 days depending on relapse time.

### Stomatology

In case of stomatitis, gingivitis and paracementitis, it is recommended to gargle with 10-15ml of Miramistin 3-4 times daily.

### **Adverse Reactions.**

In individual cases mild burning sensation at the administration site may develop, such sensation will pass away within 15-20 seconds without cure and will not require the drug discontinuation. Hypersensitivity reaction.

### **Drug-Drug Interactions**

Following the concurrent use with antibiotics, the decrease in microbial resistance to antibiotics was observed.

### **How Supplied**

Solution for local administration, 0.01 %.

50ml and 100ml polyethylene vials with urologic applicator.

50ml and 100ml polyethylene vials with urologic applicator and with spray nozzle.

50ml and 100ml polyethylene vials with urologic applicator and with a gynecological nozzle.

100ml, 150ml and 200ml polyethylene vials with spray nozzle.

500ml polyethylene vials with a dropper cap with control of the first opening.

Each 50ml, 100ml, 150ml, 200ml, 500ml vial with the instruction is placed into a cardboard packet.

For hospitals for in-patients: 12 500ml vials without an equal amount of instructions are placed into a cardboard box for the consumer packaging.

### **Storage**

Store at temperature not above 25°C.

Keep out of reach of children.

### **Exp.**

3 years. Do not use after expiry date.

### **Legal classification**

available without prescription.

### **Manufactured by:**

LLC «INFAMED»

**Organization authorized to receive claims:**

LLC «INFAMED»

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