

APPROVED
by the Order of the Ministry of
Health of Ukraine
23.03.2021 No. 548
Marketing Authorization
No. UA/18640/01/01

PACKAGE LEAFLET
for medical use of a medicinal product

VEROMISTIN®

Qualitative and quantitative composition:

Active substance: myramistin;

1 ml of solution contains myramistin 0,1 mg;

list of excipients: water for injection.

Pharmaceutical form. Topical solution.

Main physical and chemical properties: colorless transparent liquid that foams when shaken.

Pharmacotherapeutic group. Antiseptics and disinfectants. ATX code D08A J.

Pharmacological properties.

Pharmacodynamic properties.

Myramistin has a pronounced bactericidal effect against gram-positive and gram-negative, aerobic and anaerobic bacteria in the form of monocultures and microbial associations, including hospital strains resistant to antibiotics. The medicinal product is effective against gram-positive bacteria (*Staphylococcus spp.*, *Streptococcus spp.*, *Streptococcus pneumoniae*, etc.) and gram-negative bacteria (*Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella spp.*, etc.); acts on sexually transmitted diseases (*Chlamydia spp.*, *Treponema spp.*, *Trichomonas vaginalis*, *Neisseria gonorrhoeae*), as well as on herpes viruses, human immunodeficiency viruses, etc. It has an antifungal effect on ascomycetes of the genus *Aspergillus* and genus *Penicillium*, yeast fungi (*Rhodotorula rubra*, *Torulopsis gabrata*, etc.) and yeast (*Candida albicans*, *Candida tropicalis*, *Candida krusei*, etc.), dermatophytes (*Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Trichophyton verrucosum*, *Trichophyton schoenleinii*, *Trichophyton violaceum*, *Epidermophyton Kaufman-Wolf*, *Epidermophyton floccosum*, *Microsporum gypseum*, *Microsporum canis*, etc.), as well as other pathogenic fungi, such as *Pityrosporum orbiculare* (*Malassezia furfur*), in the form of monocultures and microbial associations, including fungal preparations with resistance to chemotherapeutic medicinal products. Effectively prevents infection of wounds and burns, activates regeneration processes. Stimulates protective reactions at the site of application, by activating the absorption and digestive function of phagocytes, potentiates the activity of the monocyte-macrophage system. Has a pronounced hyperosmolar activity, as a result of which it relieves wound and perifocal inflammation, absorbs purulent exudate, contributing to the formation of a dry scab. Does not damage granulation and viable skin cells, does not inhibit marginal epithelialization. It has no allergenic properties and has no local irritant effect.

Pharmacokinetic properties.

When it is used topically is not absorbed through the skin and mucous membranes.

Clinical particulars.

Therapeutic indications.

Otorhinolaryngology: comprehensive treatment of acute and chronic otitis, sinusitis, tonsillitis,

laryngitis, pharyngitis.

Dentistry: treatment and prevention of infectious and inflammatory diseases of the oral cavity: stomatitis, gingivitis, parodontitis, periodontitis. Hygienic treatment of removable dentures.

Surgery, traumatology: prevention of suppurations and treatment of purulent wounds. Treatment of purulent-inflammatory processes of the musculoskeletal system.

Combustiology: treatment of superficial and deep burns of II and III A degrees; preparation of burn wounds for dermatoplasty.

Dermatology: treatment and prevention of pyoderma and dermatomycosis, candidiasis of the skin and mucous membranes, mycosis of the feet.

Obstetrics and gynecology: prevention and treatment of suppuration of postpartum injuries, perineal and vaginal wounds, postpartum infections, inflammatory diseases (vulvovaginitis, endometritis).

Urology: comprehensive treatment of acute and chronic urethritis and urethroprostatitis of both specific (chlamydia, trichomoniasis, gonorrhea) and non-specific nature.

Contraindications.

Individual sensitivity to myramistin.

Interaction with other medicinal products and other forms of interaction.

Co-administration of antibiotics, an increase in their antibacterial and antifungal properties has been noted.

Fertility, pregnancy and lactation.

As absorption of medicinal product is almost non-existent, Veromistin® may be used during pregnancy or lactation.

Effects on ability to drive and use machines.

Veromistin® does not affect the ability to drive vehicles and engage in other potentially dangerous activities that require increased concentration and speed of psychomotor reactions.

Posology and method of administration.

The solution is ready for use. Administer topically for adults.

Surgery, traumatology, combustiology. For prophylactic and therapeutic purposes Veromistin® uses for irrigate the surface of wounds and burns, loosely tamponade the wound and fistulas, fix gauze moistened soaked in antiseptic. Repeat the treatment procedure 2-3 times a day for 3-5 days. The method of active drainage of wounds and cavities with a daily consumption of up to 1 liter of the medicinal product is effective.

Obstetrics and gynecology. In order to prevent postpartum infection, use in the form of vaginal irrigation before delivery (5–7 days), in childbirth after each vaginal examination and in the postpartum period in the form of intravaginal tampons soaked in 50 ml of the medicinal product with exposure for 2 hours for 5 days.

During childbirth by cesarean section, the vagina is treated immediately before the operation, during the operation - the uterine cavity and the incision on it, and in the postoperative period, tampons soaked in the medicinal products are injected into the vagina with exposure for 2 hours for 7 days. Treatment of inflammatory diseases of the female genital organs should be carried out in a course of 2 weeks, by intravaginal administration of tampons with the medicinal products, treatment of the skin of the external genitalia, as well as by electrophoresis.

Dermatology. Treatment of candidamycosis of the skin and mucous membranes, mycosis of the feet and large folds should be carried out by applications 2-4 times a day.

Otorhinolaryngology. At purulent sinusitis during a puncture to wash a maxillary sinus with a sufficient amount of medicinal product. In the treatment of tonsillitis, pharyngitis and laryngitis, gargle with Veromistin® solution 3-4 times a day. The amount of medicinal product per rinse is 10-15 ml. In case of otitis media, a tampon soaked in the medicinal products should be injected into the external auditory canal 4-6 times a day for 10–14 days.

Dentistry. In the treatment of parodontitis, a solution of myramistin is injected into the periodontal pockets on the turundas, followed by applications on the gums for 15 minutes. In case of exacerbations to carry out washing of Veromistin® of periodontal pockets by means of the syringe and insert turunda with the medicinal products into the abscess cavity. After vestibuloplasty and frenulectomy, the medicinal product should be used in the form of baths in an outpatient setting. In case of stomatitis, gingivitis, it is recommended to rinse the mouth with 10-15 ml of the medicinal product 3-4 times a day. For the purpose of hygienic treatment of removable dentures, leave them overnight in a solution of myramistin, rinse the dentures thoroughly with running water before using.

Urology. In the complex treatment of urethritis and urethroph prostatitis, 2-3 ml of the medicinal product is injected into the urethra 1-2 times a day, the course is 10 days.

Children.

As there is insufficient experience with the use of myramistin solution for the treatment of children, it should not be used in pediatric practice.

Overdose.

No overdose phenomenon was observed.

Undesirable effects.

In some cases, a short-term burning sensation is possible, which disappears on its own after 15-20 seconds and does not require withdrawal of the medicinal product.

Hypersensitivity reactions, in particular the phenomenon of local skin irritation: itching, hyperemia, burning sensation, dry skin.

Reported suspected adverse reactions.

Reporting suspected adverse reactions after registration of a medicinal product is an important procedure. This allows for continued monitoring of the benefit/risk ratio for the respective drug. Healthcare providers should be informed of any suspected adverse reactions through the national alert system.

Shelf life. 2 years.

Special precautions for storage.

Store in the original package at a temperature not exceeding 25°C.

Do not freeze.

Keep out of the reach of children.

Nature and contents of container. 100 mL, 200 mL or 400 mL in vials.

Category of release. Prescription only medicine.

Manufacturer. PrJSC "Pharmaceutical firm "Darnitsa".

The manufacturer's location and address of the place of business.

13, Boryspilska Street, Kyiv, 02093, Ukraine.

Date of last revision. 23.03.2021.