Instructions for using a medical device: Hydrogel coating to inhibit the development of bacterial biofilms ENTOMIX ® according to TU 32.50.50-006-72500079-2020, execution options Vamos Biotech (Shanghai) CO., LTD (

1. NAME OF MEDICAL DEVICE

Hydrogel coating to inhibit the development of bacterial biofilms ENTOMIX ® according to TU 32.50.50-006-72500079-2020, execution options:

1. Hydrogel coating for suppressing the development of bacterial biofilms ENTOMIX ® 10 ml;

2. INFORMATION ABOUT THE MANUFACTURER OF THE MEDICAL DEVICE

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3. PURPOSE OF THE MEDICAL DEVICE ESTABLISHED BY MANUFACTURER

This instruction sheet applies to Hydrogel Suppression Coating bacterial biofilm development ENTOMIKS ® TU 32.50.50-006-72500079-2020, execution options (hereinafter referred to as the hydrogel coating) is intended for creating a protective coating and suppressing the development of bacterial biofilms on damaged areas of the skin.

Indications for use:

- Pyoderma.
- purulent-necrotic skin lesions in diabetes.
- infected burns.

Contraindications:

- individual intolerance to the components of the gel.

Possible side effects:

Usually, when properly stored, transported and used according to of this instruction - there are no side effects, but itching, burning are possible.

Application conditions:

The hydrogel coating is intended for indoor use in conditions in medical institutions, as well as at home. This is an OTC product; no prescription is required for the use of this medical device.

4. DESCRIPTION OF THE PRINCIPLES ON WHICH THE WORK IS BASED ON MEDICAL DEVICES AND THEIR FEATURES

The ENTOMIX® hydrogel coating is a non-sterile wound covering made of a cross-linked amorphous hydrating gel. The gelling agent is a lightly crosslinked copolymer of acrylic acid, Carbopol, neutralized with sodium hydroxide (final pH 5.5). When applied to a damaged area of the skin, the hydrogel coating creates a film on its surface, which provides mechanical protection for the damaged area and the moisture level necessary for wound healing.

The peptide complex FLIP7 contains naturally occurring cationic peptides (defensins, cecropins, diptericin's, proline-rich peptides). FLIP7 prevents the formation of and effectively fights against bacterial biofilms formed by Staphylococcus aureus, Escherichia coli and other pathogens that colonize wounds and damaged skin areas. At the same time, FLIP7 acts on both sensitive and antibiotic-resistant bacteria and does not induce the formation of resistance. Thus, the wound dressing containing FLIP7 increases the efficiency of medical procedures aimed at removing bacteria from the wound cavity or inflammation focus, facilitates access to bacterial cells of phagocytes, antibiotics, and other antibacterial drugs.

Electrostatic interaction of positively charged groups of cationic peptides FLIP7 and negatively charged groups of carbopol creates an integrated wound covering that provides mechanical protection of the damaged surface, provides moist wound management thanks to a hydrogel base, without interfering with proper aeration, suppresses the formation of bacterial biofilms that cause inflammation of the damaged tissue and hinder it healing.

The composition of the coating of the hydrogel ENTOMIX® also contains allantoin and Euxil. Allantoin is used as an agent to maintain water balance and accelerate the regeneration of skin lesions. Euxil serves as a preservative that prevents microbial contamination of the product.

The ENTOMIX® hydrogel coating can be used in combination with additional dressings, and also as an adjuvant in antibiotic treatment. In this case, the functional purpose of the hydrogel is not realized through pharmacological, immunological, genetic, or metabolic effects on the human body.

5. METHOD OF APPLICATION

The hydrogel coating ENTOMIX® effectively prevents the formation of biofilms by microorganisms, which contributes to the uncomplicated course of the wound process. For these purposes, it is best to start using the ENTOMIX® hydrogel coating immediately after injury to the skin. Application of ENTOMIX® coating at later stages of the skin inflammatory process leads to the destruction of already formed biofilms, and further use of ENTOMIX® prevents their re-formation.

ENTOMIX® should be applied directly to the damaged surface with a thin layer (up to 1 mm) in case of:

- **infected burn - 1 time per day,**
- **purulent-necrotic skin lesions in diabetes - 1 time per day,**
- **pyoderma - 1-2 times a day.**

IMPORTANT: Before applying, it is better to treat / clean the wound, remove necrotic elements. For effective work of the coating of the hydrogel ENTOMIX®, it is necessary to apply it directly to the surface of pyoderma, burns, diabetic ulcers. It is necessary to ensure direct contact of the components of the gel with bacteria in the wound.

The term of application of the ENTOMIX® hydrogel coating is during the period necessary for the healing of the wound surface and removal of the symptoms of inflammation of the damaged area of the skin.

3 minutes after application of the coating with ENTOMIX® hydrogel, the wound can be closed with a secondary dressing (in case of burns, diabetic ulcers), which does not contain strong oxidants or proteolytic enzymes, as well as cytotoxic antiseptics.

The ENTOMIX® hydrogel coating can be used individually or as an adjuvant to increase the effectiveness of antibiotic treatment.

6. TECHNICAL DESCRIPTION OF THE MEDICAL DEVICE

Product options - hydrogel coating, hermetically packed in tubes with a volume of 10 ml. The coating is hydrogel in terms of organoleptic and physicochemical characteristics, corresponds to table 1.

Table 1.

Indicator name	**Characteristics and norm**
Appearance	Gel form, free from foreign impurities.
Color	Transparent
Smell	Neutral
PH value	5.5 -7.5
Mass fraction of dry substances (%)	not less than 1.1
Density	1.001 ± 0.010 g / cm 3

The hydrogel coating is made according to the recipe in table 2.

Table 2.

Component (manufacturer, country of origin)	Content (%)
Carbopol ("The Lubrizol Corporation", USA)	0.45
Allantoin ("Clariant Produkte GmbH", Germany)	0.1
Euxil PE 9010 ("Schülke & Mayr GmbH", Germany)	0.5
Sodium hydroxide (LLC "Nevareaktiv", Russia)	0.05
Peptide complex FLIP7 (Allofarm LLC, Russia)	0.05
Distilled water	98.85

Tube materials are identified as: low density polyethylene and polyethylene high density (tube body), polypropylene (tube lid). The delivery set of the hydrogel coating corresponds to Table 3.

Table 3.

Name	Quantity
1. Covering hydrogel ENTOMIX® according to TU 32.50.50-006-72500079-2020 volume of 10 ml.	
1.1 Covering hydrogel ENTOMIX ®, volume 10 ml.	1
1.2 Instructions for use	1
1.3 Consumer packaging	1

7. SAFETY REQUIREMENTS

- Before use, you must carefully read these instructions for use;
- Before applying the hydrogel coating, it is recommended to consult a doctor;
- Store in a dry place out of reach of children;
- The product should be stored at a low positive temperature from + 2 ° C to + 8 ° C (conditions of a household refrigerator);
- Independent use is recommended for persons over 14 years of age;
- During storage and use, the hydrogel coating does not emit toxic substances or radiation into the environment and does not have a harmful effect on the human body upon direct contact. Working with it does not require any special precautions;
- When using a hydrogel coating, special measures to protect the natural environment are not required;
- The hydrogel coating should be used separately with products containing aggressive substances (alcohol, oxidants, etc.);
- The hydrogel coating is not intended to be applied to the surface of the eye. In case of accidental contact, rinse the surface of the eye with clean water or 0.9% sodium chloride solution.

8. REQUIREMENTS FOR ENVIRONMENTAL PROTECTION DURING APPLICATION MEDICAL DEVICE

The hydrogel coating during use, transportation and storage does not have a negative impact on humans and the environment.

9. METHODS OF STERILIZATION

The hydrogel coating is supplied non-sterile. Do not use the hydrogel coating after the expiration date stated on the label. The shelf life of the hydrogel coating when the package is opened is 6 months.

10. LIST OF REGULATORY DOCUMENTS

The hydrogel coating meets the requirements of GOST R 50444-92, GOST 33756-2016, TU 32.50.50-006-72500079-2020 and a set of design documentation AFM.72500079, approved in accordance with the established procedure.

11. MARKING, PACKAGING, TRANSPORTATION CONDITIONS

The marking of the hydrogel coating is made in accordance with the requirements of GOST R 50444-92, GOST 33756-2016 and has the following information:

- product name;
- manufacturer's name;
- designation of these technical conditions;
- batch number;
- shelf life;
- date of manufacture;
- storage conditions;
- composition of product components;
- the volume of the tube;
- symbol "Consult instructions for use";
- number and date of the registration certificate.

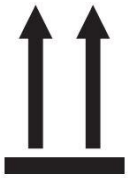
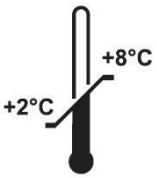
** It is possible to place advertising materials on the consumer packaging of the product.
Each shipping box or case is labeled with the following information:

- product name;
- the name or trademark of the manufacturer;
- the legal address of the manufacturer (including the country);
- designation of these technical conditions;
- date of manufacture;
- number of products;
- gross weight;
- “Keep away from moisture” symbol;
- fragile. Carefully!";
- symbol "Storage and transportation conditions";
- “Avoid exposure to sunlight” symbol.

Marking on consumer or transport packaging is carried out by printing. Permanent data is typo-graphed, while variable data can be filled in by hand, but clearly and legibly.

Shipping containers are marked in accordance with GOST 14192-96 with handling signs "Top", "Fragile. Caution! ”,“ Conditions of storage and transportation ”.

Explanation of symbols and manipulation signs:

 Refer to instructions for use	 Keep away from moisture	 Avoid exposure to sunlight
 Top	 Fragile. Careful!	 Storage conditions and transportation

Ready-to-use hydrogel coating and instructions for use are packed in a consumer package (box) with overall dimensions: for a 10 ml version - 100 × 30 × 30 mm (± 10%); made of cardboard in accordance with GOST 7933-89 or GOST 9142-2014. The production of instructions for use should be made by typographic method.

Consumer packages (boxes) in the amount of not more than 1000 pcs. are placed in a corrugated cardboard transport box in accordance with GOST 13511-2006 or GOST R 54463-2011.

The transport box is covered with polyethylene tape with a sticky layer (scotch tape) in accordance with GOST 20477-86 or tied with twine in accordance with GOST 17308-88.

Each shipping box contains a packing list indicating the manufacturer, the name and quantity of packaged products, as well as the conditional number or full name of the packer, the QCD inspector and the date of manufacture.

The weight of each transport box (gross) is no more than 8 kg.

Transportation of the hydrogel coating is carried out in covered vehicles by any type of transport in accordance with the rules for the carriage of goods in force for this type of transport.

Hydrogel coatings, packed in accordance with the requirements of TU 32.50.50-006-72500079-2020, during transportation are resistant to mechanical factors in accordance with GOST R 50444-92 for storage conditions 1 in accordance with GOST 15150-69.

Hydrogel coatings (with closed and opened packaging) are stored in dry, clean, closed places in conditions that ensure the safety of medical devices at temperatures from + 2 ° C to + 8 ° C and humidity not more than 80%.

12. MAINTENANCE AND REPAIR

The hydrogel coating is not subject to maintenance and repair.

13. WARRANTY OBLIGATIONS

The manufacturer guarantees the compliance of the hydrogel coating with the requirements of TU 32.50.50-006-72500079-2020, subject to the conditions of operation, transportation, and storage.

The guaranteed shelf life of the hydrogel coating is 2 years.

The shelf life of the hydrogel coating when the package is opened is 6 months.

14. PROCEDURE FOR DISPOSAL OR DESTRUCTION MEDICAL DEVICE

Disposal of the hydrogel coating is carried out in accordance with the rules and regulations of SanPiN 2.1.7.2790-10 "Sanitary and Epidemiological Requirements for Handling Medical Waste", as class A medical waste. At home, the hydrogel coating and / or its packaging is disposed of together with household waste.

15. COMPLAINTS

Complaints should be sent to the address of the manufacturer:

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