

PACKAGE INSERT

1. Product Name: MestaMidin-sens

Generic Name or INN: Octenidine dihydrochloride + Phenoxyethanol
Brand Name: MestaMidin-sens

2. Name and Strength of Active Ingredient (s)

1 ml of product contains:

Active ingredients:

Octenidine dihydrochloride – 1.0 mg

Phenoxyethanol – 20.0 mg

Excipients:

Sodium chloride – 0.5 mg

Propylbetainamide – 3.0 mg

of coconut fatty acids

(Cocamidopropylbetaine)

Sodium gluconate – 4.0 mg

Glycerol anhydrous – 5.0 mg

0.05 M sodium hydroxide – up to pH 5.0 – 7.0

solution or 0.05 M

hydrochloric acid solution

Water for injection – up to 1 ml

3. Product Description

Clear or slightly transparent, colorless or slightly tinged liquid free of visible particulate matter. Polymer bottles containing 50, 100 or 150 ml of the solution provided with a dropper or pump and sprayer. 1 bottle with a package insert in a carton.

4. Pharmacodynamics / Pharmacokinetics

MestaMidin-sens has a broad-spectrum antimicrobial effect, antimycotic and antiviral activity due to hydrophobic interactions between octenidine dihydrochloride and phenoxyethanol and cell membranes of pathogenic microorganisms. The antimicrobial activity involves spore and non-spore-forming microflora, gram-positive and gram-negative bacteria (aerobic and anaerobic), dermatophytes and Candida fungi, lipophilic viruses, mycoplasma, ureaplasma. No resistance to MestaMidin-sens develops in a short- or long-term use. It has no toxic effect, is not almost adsorbed through mucous membranes, the skin or wound surfaces; it destroys microorganisms without cell damage. Its use enables wound and burn healing.

5. Indication

-Treatment of the skin and mucous membranes in pediatric, surgical and obstetric and gynecologic practice, in traumatology, proctology, dermatology and venereology, otolaryngology and dentistry.

-For treatment of wound and burn surfaces.

-Prevention of foot and interfinger mycosis.

Without age limit in pediatric practice.

6. Recommended Dose

Surgery, traumatology, proctology, pediatrics

Irrigate the skin and mucous membranes for preventive and therapeutic purposes.

The affected surface must be treated in full. Apply the medication to a difficult accessible area by spraying. The exposure time should not be less than 1-2 min.

Obstetrics and gynecology

Disinfection of birth canal

Disinfect the birth canal by irrigation with an undiluted solution once a day, for 5-7 days.

Disinfection of operative field

Before surgery treat the operative field with a sterile cloth, richly moistened with the product, or irrigate it. The surface should be treated twice.

Hand scrubbing

Before using the product, wash the hands and forearms thoroughly with warm water and soft soap for 2 minutes, dry with a sterile gauze cloth. Apply the product to thoroughly washed and dried hands (3-5 ml at least twice), the exposure time is 5 min. Put sterile gloves on the dry hands only.

Breast nipple treatment

To prevent or treat cracked nipples apply the product on the nipples immediately after breast feeding. Wipe the breasts with a cloth moistened with boiled water prior to the next feeding.

Prevention of sexually transmitted diseases (STD)

To prevent STD use the product not later than 30 min after the sexual intercourse. Irrigate or wipe the skin and mucous membranes of the external genitalia excessively with a moistened cotton swab.

Treatment of the skin and mucosa in newborn

Use MestaMidin-sens undiluted to treat an umbilical wound or the skin prior to the placement of venous cannulas, central venous catheters, peripheral catheters, by irrigation or wiping with a swab, abundantly moistened with the antiseptic.

Treatment of postsurgical sutures

Irrigate postsurgical sutures or wipe them with a swab abundantly moistened with the antiseptic, twice a day for 5-7 days.

Otolaryngology

Adults.

Irrigate the oral cavity 3-4 times a day.

Use 20 ml of the product for 20 sec to gargle the oral cavity and the throat. MestaMidin-sens can be diluted in the ratio of 1:1 (1 part of the product and 1 part of drinking water).

It is recommended to gargle the mouth and throat only to the patients who can do it themselves.

Children.

Children aged 3-6 years: Treat the oral cavity with a swab moistened with the product (3-5 ml) 3-4 times a day.

Children aged 7-14 years: Gargle the oral cavity (5-7 ml) 3-4 times a day. MestaMidin-sens can be diluted in the ratio of 1:1 (1 part of the product and 1 part of drinking water).

Children older than 14 years: Irrigate the oral cavity 3-4 times a day. Use 20 ml of the product for 10 sec to gargle the oral cavity and the throat. MestaMidin-sens can be diluted in the ratio of 1:1 (1 part of the product and 1 part of drinking water).

The duration of therapy ranges from 4 to 7 days depending on the time of remission.

Dentistry.

It is recommended to wash the mouth and throat only to the patients who can do it themselves. Use 20 ml of the product for 20 sec to gargle the oral cavity and the throat. The contact time should not be longer than 1 min.

If the patient cannot gargle the mouth him/herself, wipe the oral cavity and throat with a moistened swab. In this case the contact time should not be longer than 2 min. Ensure in

any case that the product did not get into the airways.

MestaMidin-sens can be diluted in the ratio of 1:1 (1 part of the product and 1 part of drinking water).

Consult your physician if your condition did not improve, your symptoms worsen, or new symptoms occurred after treatment. Use the product only for the indications, follow the method of administration and the doses that are specified in the package insert.

Do not use the product for more than 14 days.

7. Mode of Administration

Local and external use

8. Contraindications

Hypersensitivity to components of the product. Do not use for abdominal lavage (during surgery, for example), in the area of the tympanic membrane or for intravesical instillation.

9. Warnings and Precautions

Prevent MestaMidin-sens contact with eyes! In case of accidental ingestion of a significant amount of the product, carry out the stomach lavage with plenty of water and take activated carbon.

Do not swallow MestaMidin-sens when gargling the mouth.

In order to prevent tissue damage, it is prohibited to inject the product into the tissue under pressure, especially with a syringe. Drainage should be always provided.

10. Interactions With Other Medicaments

Do not use MestaMidin-sens in combination with iodine-containing antiseptics as the skin color in adjacent areas can change from brown to purple.

If you use the above or other medications (including over-the-counter products), consult your physician before using MestaMidin-sens.

11. Pregnancy and Lactation

The product might be used in pregnancy and breast feeding if a potential benefit to the mother outweighs any potential risk to the fetus or the baby.

Pregnancy

There are limited data on using the product in pregnant women (from 300 to 1,000 pregnant women, the gestational age ≥ 12 weeks) which indicate no drug effects on the development of congenital malformation or its toxicity to the embryo/fetus (developmental toxicity).

There was no evidence of reproductive toxicity in animal studies.

Breast feeding

As octenidine dihydrochloride is not absorbed or is absorbed in a very small amount, it is not supposed to penetrate into breast milk.

Phenoxyethanol is rapidly and almost completely absorbed and eliminated almost completely as an oxidation product by the kidneys, it is unlikely to accumulate in breast milk.

As a precaution it is recommended to not treat the breast surface with MestaMidin-sens immediately prior to breast feeding.

Consult your physician before using the product in pregnancy or breast feeding.

12. Undesirable Effects

Adverse events (AEs) are distributed by the frequency of their occurrence. The frequency is estimated as follows: very often ($\geq 1/10$); often ($\geq 1/100$, $< 1/10$); not often ($\geq 1/1,000$; $< 1/100$); rarely ($\geq 1/10,000$; $< 1/1,000$); very rarely ($< 1/10,000$), including individual reports. The AEs are ranked in a descending order of severity within each group of frequency.

General disorders and reactions of the administration site:

Rarely: burning, redness (erythema), itching, a warm feeling at the site of application.

Very rarely: contact allergic reaction, for example, temporary erythema (redness) at the site of application.

There may be a bitter taste when gargling the mouth.

Side effects such as swelling, induration, pain, blistering, eczema in the area of application may occur.

Pediatric population

The frequency, type and severity of adverse reactions in children are the same as those in adults.

Improper use (for example, injections in tissues, see "Special Warnings") may result in edema and tissue damage up to necrosis.

Inform your physician if you have side effects enlisted in the package insert, they become worse, or you have any other side effects non-specified in the leaflet.

13. Overdose and treatment

Overdosage is unlikely to occur if the drug is used according to the package insert. Wash the treated area with a large volume of the Ringer's solution in case of overdosage when applied topically. Symptoms management is indicated in case of accidental intake of the drug.

14. Dosage Forms and Packaging Available

Solution for local and external use. Polymer bottles containing 50, 100 or 150 ml of the solution provided with a dropper or pump and sprayer. 1 bottle with a package insert in a carton.

15. Name and Address of Manufacturer

LLC «Grotex», Russia
195279, Saint-Petersburg,
Industrialny Prospekt 71, bld. 2, lit. A
Phone: +7 812 385 47 87
Fax: +7 812 385 47 88.
www.solopharm.com

Name and Address of Marketing Authorization Holder

LLC «Citera», Russia
195279, Saint-Petersburg,
Industrialny Prospekt, 71, bld. 2, lit. A