

Octenisept® Antiseptic Solution

Octenidine hydrochloride, Phenoxyethanol (0.1% (w/w), 2.0% (w/w))

What is in this leaflet

1. What *Octenisept Antiseptic Solution* is used for
2. How *Octenisept Antiseptic Solution* works
3. Before you use *Octenisept Antiseptic Solution*
4. How to use *Octenisept Antiseptic Solution*
5. While you are using it
6. Side effects
7. Storage and disposal of *Octenisept Antiseptic Solution*
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Octenisept Antiseptic Solution* is used for

250 ml & 500 ml:

Octenisept is indicated for:

- Repeat short term antiseptic treatment of mucous membranes and adjacent tissues prior to diagnostic and minor surgical procedures in the anogenital region, including the vagina, vulva and glans penis as well as prior to bladder catheterization.
- Superficial treatment of wounds (including minor burns).

50 ml:

Octenisept Antiseptic Solution is a broad spectrum antiseptic to help treat and prevent infection in minor cuts, wounds, abrasions and minor burn burns.

How *Octenisept Antiseptic Solution* works

This medicine is a topically applied antiseptic that works locally.

Octenidine hydrochloride reacts with cell wall and membrane components of microbial cells leading to the destruction of cell function.

Phenoxyethanol antimicrobial activity is partly based on increased permeability of the cellular membrane for potassium ions.

Before you use *Octenisept Antiseptic Solution*

- When you must not use it

To prevent possible tissue injury, *Octenisept* must not be injected into the deep tissue using a syringe. *Octenisept* is intended for superficial use only (application by swab or spray pump) and must not be used to irrigate penetrating wounds.

Do not use *Octenisept* if:

You are hypersensitive to, or have had an allergic reaction to, Octenidine hydrochloride, Phenoxyethanol, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- fatigue, dizziness, lightheadedness, fainting, palpitations or altered heart beat
- rash, hives or flushed, red skin

If you think you are having an allergic reaction, do not use any more of the medicine and tell your doctor or nurse immediately or go to the Accident and Emergency department at the nearest hospital. In case of contact with the eyes rinse immediately with plenty of water. It should not be used if the expiry date printed on the label is overdue.

Do not use unless tamper proof seal is intact.

If you are not sure whether you should use *Octenisept Antiseptic Solution*, talk to your doctor.

- Before you start to use it

Tell your doctor if:

- you are allergic Octenidine hydrochloride, phenoxyethanol, or to any other medicine, foods, preservatives or dyes.
- you are pregnant or plan to become pregnant or are breast-feeding.
- you are using any other medicine

Your doctor can discuss with you the risks and benefits involved.

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop, such as soaps, creams or lotions.

How to use *Octenisept Antiseptic Solution*

- How much to use

50 ml & 250 ml: Spray *Octenisept Antiseptic Solution* directly onto area to be treated.

500 ml: Swab *Octenisept Antiseptic Solution* directly onto area to be treated.

Ensure the area is thoroughly moistened and then leave to dry. The treated area may be covered with a bandage if required.

- When to use it

Follow the instructions from your doctor or pharmacist.

- How long to use it

Following application and prior to further measures, such as e.g. the application of a wound dressing, an exposure time of at least 1 minute for mucous membranes and wounds and 2 minutes for the adjacent skin with a minimum of 1 minute drying time must be observed.

Octenisept applied once a day for a duration of up to 14 days.

These instructions must be carefully followed in order to achieve the desired effect.

- If you forget to use it

Use it as soon as you remember. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not apply a double dose to make up for the missed dose.

- If you use too much (overdose)

There is no knowledge of cases of overdose. However, overdosing of a topical preparation is very unlikely. In the case of local overdose, the affected areas can be rinsed with plenty of Ringer's solution.

While you are using it

- Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are using *Octenisept Antiseptic Solution*

- Things you must not do

To prevent possible tissue injury, *Octenisept* must not be injected into the deep tissue using a syringe. *Octenisept* is intended for superficial use only (application by swab or spray pump) and must not be used to irrigate penetrating wounds.

- Things to be careful of

Discontinue use if irritation or sensitivity reaction develops.

Side effects

Tell your doctor immediately if:

- develop a rash, hives red or tingling skin after being given *Octenisept*
- experience burning, redness, itching and warmth at the application site

- experience persistent edema or erythema at the application site
- have an allergic contact reaction, e.g. temporary redness at the application site

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of *Octenisept Antiseptic Solution*

- Storage

Store the product below 30°C. Keep out of reach of children.

- Disposal

Dispose the medicine after the expiry date. Consult your pharmacist on how to safely dispose of any medicines no longer required.

Product description

Octenisept Antiseptic Solution is an aqueous solution for topical administration. This solution is a clear, colourless, almost odourless liquid.

- Ingredients

Active ingredients:

Octenidine hydrochloride 0.1% (w/w)

Phenoxyethanol 2.0% (w/w)

Inactive ingredients:

Cocamidopropylbetaine, sodium gluconate, glycerol, sodium chloride, sodium hydroxide and purified water.

- MAL number:

MAL24066033X

Manufacturer and Product Registration Holder

- Manufacturer

Schulke & Mayr GmbH
Robert-Koch-Straße 2
22851 Norderstedt
Germany

- Product Registration Holder

Galla Med Sdn Bhd
No 40-1, Jalan Rimbunan Raya
Laman Rimbunan Kepong
52100 Kuala Lumpur

Date of revision

20/02/2024

Serial Number

NPRA (R2) 23/211