

# schülke -}

Antiseptic for the treatment of bacterial and fungal infections in the vaginal area

# octenisept<sup>®</sup> vaginal therapeutic agent

### **Our Plus**

- for the treatment of bacterial and fungal infections\*
- helps with recurrent infections
- includes vaginal applicator for easy application
- no restrictions on use in the partner and pregnant women\*\*
- octenisept<sup>®</sup> vaginal therapeutic agent is colourless no unpleasant stains on the laundry

#### **Application areas**

Application in order to relieve the symptoms of itching, burning and discharge in the vaginal area caused by bacterial and fungal infections (candidiasis).

#### Instructions for use

Apply octenisept vaginal solution in the morning and evening on the first day of treatment, then once a day thereafter. The treatment period is seven days.

Before the first application, first remove the protective cap and spray cap from the bottle and store them in a safe place. Afterwards, remove the vaginal applicator from its packaging and place it on the bottle.

Before the first use, press the spray pump eight times to ensure correct dosage. Before each subsequent use, simply place the applicator on the bottle and press the spray head until some solution comes out.

For use while sitting on the toilet, insert the vaginal applicator deep into the vagina and press the spray pump ten times successively.

After use, hold the applicator downwards and spray some of the product out, for example, over the sink. Afterwards, rinse off the applicator under running water and dry it with a clean cloth.

To prevent possible re-infection, it is recommended that the partner is also treated. In the case of a male partner, spray the solution without the vaginal applicator, but with the spray cap on, onto the male genital until complete wetting. If the symptoms persist or recur after completing the treatment, a gynaecological examination is essential. In some countries, the vaginal applicator is available separately from the vaginal solution.

In the guideline of the Association of the Scientific Medical Societies (AWMF) of the German, Austrian and Swiss Societies of Gynecology (S2k), octenidine and octenisept vaginal solution are recommended as antiseptic therapy options for the treatment of bacterial vaginosis. (015-028, Status June 2023)

According to the AWMF guideline of the German, Austrian and Swiss Societies of Gynecology (S2k), octenidine is recommended as an antiseptic therapy option for vulvovaginal candidiasis. (015-072, Status September 2020)

# octenisept<sup>®</sup> vaginal therapeutic agent

# **Product data**

**Composition:** 100 g solution contain: active pharmaceutical ingredients: 0.1g octenidine dihydrochloride, 2.0g phenoxyethanol (Ph.Eur.) **Other ingredients:** cocamidopropylbetaine, sodium-D-gluconate, glycerol 85%, sodium chloride, purified water, sodium hydroxide

#### **Chemical-physical data**

Color	colourless	
Density	ca. 1,005 g/cm3 / 20 °C	
Flash point	Not applicable	
Form	liquid	
рН	6/ 100 %/ 20°C	
Viscosity, dynamic	No data available	

# **Special advice**

- · Do not swallow octenisept<sup>®</sup> vaginal solution.
- Do not enter it into the blood circuit, e.g. by being accidently injected.
- Do not use octenisept<sup>®</sup> vaginal solution in combination with PVP-iodine based antiseptics as it may cause strong brown to purple discolouration.
- In rare cases, a temporary burning sensation may occur as a subjectively experienced symptom when using octenisept<sup>®</sup> vaginal solution.
- After the first use: Dispose the residual solution remaining in the container after termination of the treatment.
- Keep octenisept® vaginal solution out of the sight and reach of children.
- As a general prinicple: administrating of any pharmaceuticals within the first trimester of pregnancy should be carried out under strict indication and medical supervision.
- Usage of octenisept<sup>®</sup> vaginal solution in the eye should be avoided. In case of contact with eyes, rinse immediately with plenty of water.
- Do not freeze.

# Information for order

ltem	Delivery form	ltem no.
octenisept Vag.therap. 50 ml FL	20/Carton	on request

These products are not available in every country. For more information please contact our local subsidiary or distributor.

# **Environmental information**

schülke manufactures products economically and with advanced, safe and environmentally friendly production processes while at the same time maintaining out high quality standards.



Schülke & Mayr GmbH holds a Manufacturer's Authorisation according to sect 13 para 1 German Drug Law and Certificates of GMP Compliance for medicinal products. schülke Headquarters Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt, Germany Phone +49 40 - 52100 - 0 Fax +49 40 - 52100 - 318 www.schuelke.com info@schuelke.com

# **Expert opinion and information**

Please visit our website for an overview of all available literature/reports on the product: www.schuelke.com. For individual questions: Customer Sales Service Phone: +49 40 52100-666 E-Mail: info@schuelke.com

\*candidiasis \*\*from the 4th month

#### octenisept® vaginal therapeutic agent

**Composition:** 100 g solution contain: octenidine dihydrochloride 0.1 g, phenoxyethanol (Ph.Eur.) 2.0 g. Other ingredients: cocamidopropylbetaine , sodium D-gluconate, glycerol 85%, sodium chloride, sodium hydroxide, purified water. **Indications:** Antiseptic treatment of the vaginal area. Relief of symptoms of itching, burning and discharge caused by bacterial infection in the vaginal area. **Contraindications:** octenisept\* Vaginal Solution may not be used in cases of hypersensitivity to any of the components of the preparation. Adequate experience has not yet been gained concerning use in children below the age of 8 years. **Undesirable effects:** In rare cases transient signs of local intolerance such as a slight burning sensation, redness or itching may occur at the application site. **Special warmings and special precautions for use:** Do not swallow octenisept\* Vaginal Solution and do not allow octenisept\* Vaginal Solution to pass into the circulation, e.g. as a result of accidental injection. Usage of octenisept\* Vaginal Solution in the eye should be avoided. In case of contact with eyes, rinse immediately with plenty of water. If any of the side effects get serious, or if you notice any side effects not listed in this user information, please tell your doctor or pharmacist.

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