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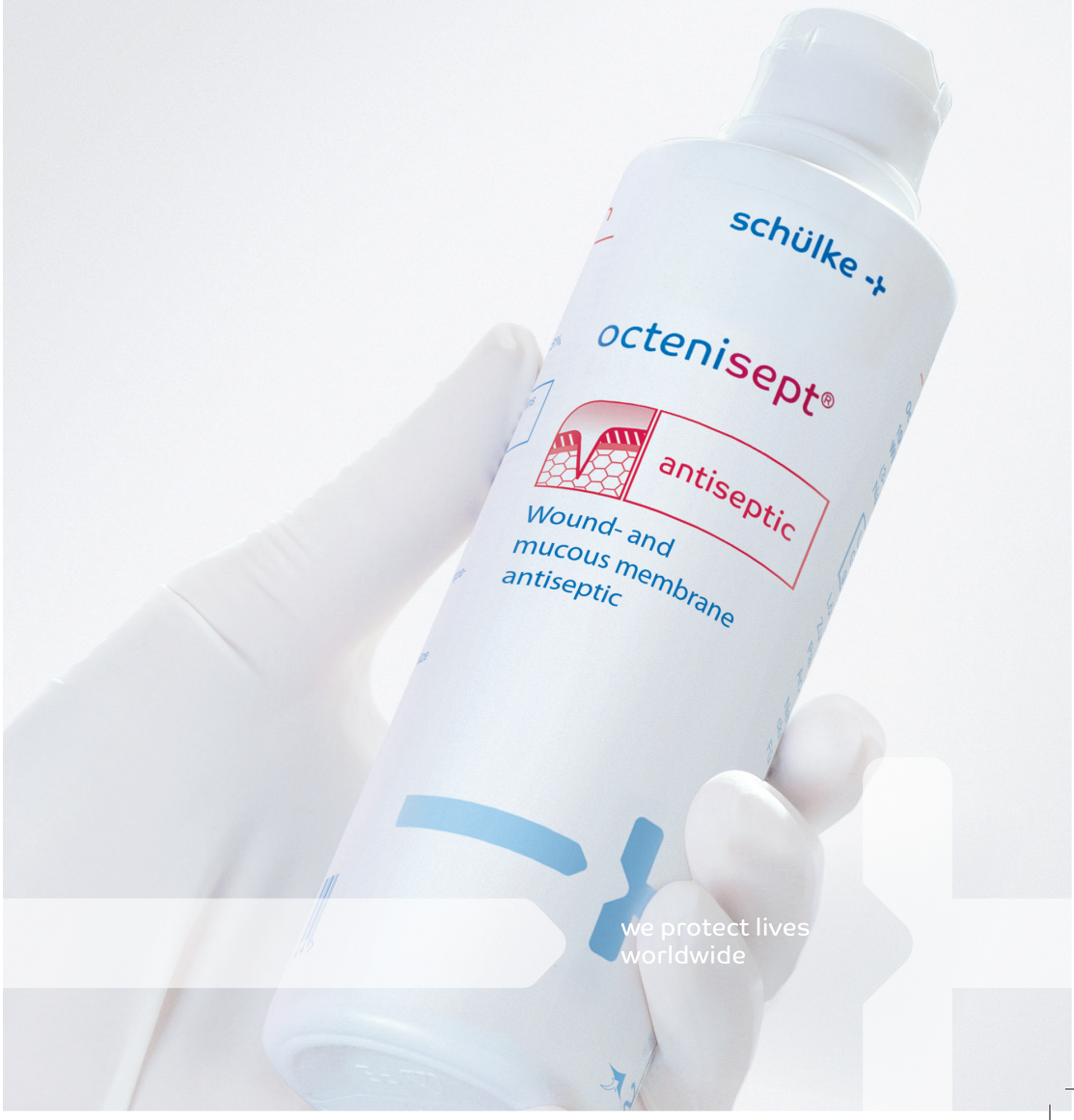
octenisept® FAQ

Answers to frequently asked questions.



we protect lives
worldwide

Questions on effectiveness

Is octenidine effective against MDRO?

Yes. Octenidine is effective against many multidrug resistant organisms (MDROs) such as MRSA, VRE and ESBL. In no study has a difference been found between resistant and sensitive strains of the same microbial species. Up to now no case has been reported in which resistance to octenidine occurred.[1, 2, 3, 4] These *in-vitro* findings are supported by clinical success when using octenisept® for the decontamination of patients.[5]

Is octenisept® effective against skin fungi?

Yes. octenisept® demonstrates good effectiveness as a fungicidal preparation against a variety of different fungi *in vitro*. In a clinical trial the preparation turned out to be effective against athlete's foot.[3]

Can octenidine penetrate the biofilm in the wound?

Yes. Octenidine is able to penetrate through the biofilm and kill the microbes in the biofilm. Evidence of this ability has been obtained both in models and in practice.[6, 7, 8]

Does octenisept® only work as an antiseptic or does it also have a cleansing effect?

octenisept® has a cleansing effect too. The preparation contains small amounts of a surfactant that acts to reduce the surface tension. This ensures that the wound surface is covered evenly and thus supports cleansing. If the wound is only to be cleaned, we recommend the octenilin® wound irrigation solution, which has a particularly low surface tension.

Questions on tolerance and compatibility

Can the use of octenisept® lead to an electrolyte shift in the wound environment resulting in a disturbance of wound healing?

No. Even if octenisept® is not isotonic it is not likely to exert a negative influence on important salts and electrolytes in the wound. Currently, no cases are known in which wound healing was upset by repeated use for a limited period of time. In a comparison with Ringer's solution, even several weeks of daily use on chronic wounds did not lead to disturbances of wound healing. The opposite was the case: Granulation was actually stimulated when octenisept® was used.[9]

Is octenisept® cytotoxic?

No. octenisept® has been authorised as a medicinal product to support the treatment of wounds since 1995. It is effective and also has very good local tolerability. In preclinical and clinical studies the preparation has been found to have no negative effects on cells and tissue when used correctly.
The description "cytotoxic" results primarily

from studies of cell cultures (in other words cells *in vitro*) and is not fully applicable to the clinical situation. Like polyhexanide and PVP-iodine, octenidine – and thus octenisept® – demonstrates these negative effects on isolated cells in cell cultures.

In relation to the antimicrobial effectiveness, however, this cytotoxicity is expressed least strongly by octenidine. [10]

In order to examine the discrepancy between the results from cell culture and the good clinical tolerability, more practice-oriented tests were carried out on tissue cultures. In these tests octenidine interacted strongly with cells and proteins. The complexes that were formed in this way reduced the cytotoxicity without harming the antimicrobial efficacy.[11] In a preclinical study on the influence on wound healing, the good tolerability of octenisept® was demonstrated.[12] In this study, artificial standardised wounds of female piglets were treated with octenisept® or Ringer's solution every day for 28 days. The results showed no difference between the two groups in the times at which the wounds healed. No difference in tissue tolerability was apparent between octenisept® and Ringer's solution. These results are supported by clinical investigations[9] and also by the results of many years' use of octenisept® with very different wound types. octenisept® was also found to have no negative influence on the healing of burns.[13]

The conclusion to be drawn from this evidence is that the cytotoxicity shown by octenisept® in cell cultures has no clinical relevance if the preparation is used correctly.

Have incompatibilities, e.g. toxic effects, between octenisept® and silver preparations been observed?

No. In this context incompabilities are not known.

Does octenisept® cause allergic reactions?

Allergic reactions on contact have been reported in only very rare cases. In relation to the frequency of use these were very rare and were only caused by octenidine in exceptional cases.[14]

Does octenisept® enter the blood stream through wound treatment?

No. If octenisept® is used correctly – in other words as a surface antiseptic for wounds – product constituents are unlikely to cross over into the tissue or the blood in quantities that are toxicologically relevant. No systemic side effects have so far been found.

Questions on areas of application

May octenisept® be used as an antiseptic for both mucous membranes and wounds?

Yes. octenisept® was approved for use as a mucous membrane antiseptic in Germany in 1990. An extension of indications for supportive wound treatment followed in 1995. Both areas of application are therefore included in the pharmaceutical marketing authorisation.

Is octenisept® suitable for intraoperative treatment of large-area wounds?

Yes. octenisept® is authorised for supportive treatment of wounds without any specifications as to the size of the wound. Because Octenidine is practically not absorbed via wounds this also justifies the surface treatment of wounds covering a large area (such as burns) without a systemic risk occurring for the patient.

Is octenisept® approved for irrigation of the abdominal cavity?

No. This is a contraindication and must be avoided.

Can octenisept® be applied to cartilage?

No. Products with cationic active ingredients such as octenidine should not be used on intact, vital cartilage tissue. Wounds in which there is contact with bone are not affected by this restriction.

Can octenisept® be used in children, babies and premature infants?

Yes. There are no restrictions on use in this regard, unlike those for other active substances such as PVP iodine. For babies and preterm infants, common precautions of use have to be followed to ensure safety. For further information please refer to package leaflet or SmPC.

Can octenisept® be used in the genital area?

Yes. octenisept® has been in use as a genital and vaginal antiseptic (e.g. before urological and gynaecological procedures) for longer than in any other area.

Can octenisept® be used for umbilical care?

Yes. In a multicentre study supported by the health ministry in Serbia, about 1,700 newborn babies were treated with octenisept®. The preparation was well-accepted. There were no signs that the umbilical stump dried out during the period of use.[15]

Can octenisept® be used for bladder irrigation?

No. This is a contraindication and must be avoided.

Can octenisept® be used in the oral cavity?

Yes. octenisept® has a marketing authorisation for preventive treatment in the oral cavity and for reducing the number of bacteria in the oral cavity before operations, e.g. tooth extractions. octenisept® induces higher rates of bacterial reduction than, for example, Chlorhexidine or PVP iodine.[16]

Can octenisept® be used for disinfection of the outer ear and the ear canal?

Yes. The external ear including its inner part can be disinfected with octenisept® In this process care must be taken to ensure that the eardrum is intact and that the product cannot get into the middle ear. Application into the middle ear is contraindicated.

Kann octenisept® be applied in the eyes?

No. This is a contraindication and must be avoided.

Can octenisept® be applied in the nose?

No. octenisept® is not approved for prophylactic or therapeutic antiseptic application to the nasal mucous membrane.

Can octenisept® be used for hand disinfection?

No. octenisept® does not meet the VAH / DGHM requirements for hand disinfectants.

Can octenisept® be used for the disinfection of catheter exit sites?

Yes. As a wound antiseptic octenisept® is suitable for the antiseptic care of skin entry sites. octenisept® does not attack the material of catheters and tubes. In practice material damage can be excluded as long as care is taken to ensure that the preparation can dry off freely.

Alternatively the remainder can be dried with a sterile cloth after it has been allowed to act for the required period of time.

Questions on application methods

Can octenisept® be warmed before application?

Yes. If larger quantities are to be applied octenisept® can be warmed to body temperature (e.g. with a bottle-warmer for baby food). This will prevent disturbance of wound healing due to local cooling. It is also more comfortable for the patient.

Can a large MRSA-colonised stomach wound with intact fascia also be treated with octenisept® and packed twice daily?

Yes. As long as it is ensured that the wound cavity is freely accessible and the preparation can drain freely. The use of pressure to force octenisept® into the wound cavities must be avoided. Irrigation of the entire abdominal cavity is contraindicated.

Can octenisept® be diluted?

No. octenisept® is an approved medicinal product that should not be diluted. For wound irrigations (e.g. during initial wound management and dressing changes) as well as for the combination with negative pressure wound therapy with instillation – within the scope of the registered indications of the negative pressure wound therapy – the octenilin® wound irrigation solution can be used instead.

Questions on duration of application

Can octenisept® be used until epithelialisation?

Yes, if medically necessary. Wounds with an undisturbed granulation and epithelialisation do not as a rule require further antiseptic measures. Based on experience octenisept® can also be applied to these wounds if there is an increased infection risk in these phases, without the risk of disturbed wound healing.

For how long can octenisept® be used?

octenisept® is approved for a maximum use period of 14 days. This period covers continuous daily use. Normally, the product is not used daily but e.g. is limited to the change of dressing. In these cases longer use is also possible. A clinical study is also available describing twelve weeks of use in chronic ulcers.[17]

How long can octenisept® be used after opening?

Containers of octenisept® can be used for up to 3 years after opening.

Questions on application with dressings

How often must the dressings be changed when octenisept® is used?

Every 12 – 24 hours. Based on proven residual effect of 24 hours for octenisept®, continuous effectiveness under a dressing can also be assumed after placing it. Change intervals depend on the condition and the exudation of the wound. If the wound continues to show local signs of infection, or if the wound continues to be at risk of infection, it is recommended to repeat the treatment with octenisept® during the next dressing change.

Can octenisept® be used for wetting Aquacel, Tenderwet or other dressing materials?

Yes. octenisept® is highly suitable for these materials.

Do you need to use silver dressings when using octenisept®?

No. As a remanent substance, octenidine remains in the wound for a longer time, extending its effectiveness beyond the actual area of application. Therefore it is not necessary to combine silver dressings with octenisept®.

Other questions

Do PHMB based wound irrigation solutions work in the same way as octenisept® as an antiseptic?

No. These wound irrigation solutions are used as a medical device for wound cleansing, and not as an antiseptic. The same is true for octenilin® wound irrigation solution. In contrast, octenisept® as an antiseptic for the supportive treatment of infected wounds is a registered drug, with a clear focus on its fast anti-microbial efficacy.

Sources:

[1] Al-Doori, Z.; Goroncy-Bermes, P.; Gemmell, C.G. *et al:* Slow-level exposure of MRSA to octenidine dihydrochloride does not select for resistance. J Antimicrob Chemother. 2007; 59: 1280-1282.

[2] Goroncy-Bermes, P.; Brill, F.H.H.; Brill, H.: Antimicrobial activity of wound antiseptics against Extended-Spectrum Beta-Lactmase-producing bacteria. Wound Med. 2013 ; 1 : 41-43

[3] Koburger, T.; Hübner, N.O.; Siebert, J.; *et al:* Standardized comparison of antiseptic efficacy of triclosan, PVP-iodine, octenidine dihydrochloride, polyhexanide and chlorhexidine digluconate. J Antimicrob Chemother. 2010 ; 65 : 1712-1719

[4] Amalaradjou, M.A.R.; Venkitananrayanan, K.; Antibiofilm Effect of Octenidine Hydrochloride on *Staphylococcus aureus* MRSA and VRSA. Pathogens. 2014 ; 3 : 404-416

[5] Krishna, B.V.S.; Gibb, A.P.: Use of octenidine dihydrochloride in methicillin-resistant *Staphylococcus aureus* decolonisation regimes - a literature review. J Hosp Infect. 2010 ; 74; 199-203

[6] Cutting, K.F.; Westgate, S.J.: The use of wound cleansing solutions in chronic wounds. Wounds UK. 2012 ; 8 : (4). 130-133

[7] Westgate, S.J.: In Vitro Evaluation of the single and multispecies biofilm prevention capabilities of two wound irrigation solutions and a topical antiseptic. Leczenie Ran. 2014 ; 11 : (3) : 109-113

[8] Harbs, N. ; Siebert, J.: In vitro efficacy of octenidine and polihexanide against biofilms composed of Pseudomonas aeruginosa. GMS Krankhaushyg Interdiszip. 2007; 2: (2); Online Document.

[9] Vanscheidt, W.; Bär, M.; Siebert, J.; *et al:* Affecting the Wound Healing Process of Chronic Ulcera by an Octenidine based Wound Antiseptic – An Explorative Analysis of a controlled clinical trial.

[10] Müller, G.; Kramer, A.: Biocompatibility index of antiseptic agents by parallel assessment of antimicrobial activity and cellular cytotoxicity. J Antimicrob Chemother. 2008; 61 : 1281-1287

[11] Kramer, A.; Müller, G.; Assadian, O.: Indikationen und Wirkstoffauswahl zur antiseptischen Therapie sekundär heilender Wunden. GMS Krankhaushyg Interdiszip. 2006; 1: (1); Doc32. Online Document.

[12] Kramer, A.; Roth, B.; Müller, G.; *et al:* Influence of the Antiseptic Agents Polihexanide and Octenidine on FL Cells and on Healing of Experimental Superficial Aseptic Wounds in Piglets: A Double-Blind, Randomised, Stratified, Controlled, Parallel-Group Study. Skin Pharmacol Physiol. 2004; 17: 141-146

[13] Menke, H.; Pelzer, M.; Siebert, J.; *et al.:* A new local antiseptic for topical treatment in patients with severe burns. Akt Traumatol. 2001; 31: 211-215

[14] Calow, T.; Oberle, K.; Bruckner-Tuderman, L.; *et al:* Contact dermatitis due to use of Octenisept in wound care. JDDG. 2009; Band 7.DOI: 10.1111/j.1610-0387.2009.07035.

[15] Jovanovic LS, Kotevic A. The use of octenisept-spray in treatment of unbilical stump and women in newborns. Belgrad, Serbien 2006 (internal report)

[16] Pitten, F.A.; Kramer, A.: Antimicrobial efficacy of antiseptic mouthrinse solutions. Eur J Clin Pharmacol. 1999; 55: 95-100

[17] Vanscheidt, W.; Harding, K.; Siebert, J.; *et al:* Effectiveness and tissue compatibility of a 12-week treatment of chronic venous leg ulcers with an octenidine based antiseptic - a randomized, double-blind controlled study. Int Wound J. 2011 : 9 : 316-323

[18] Lutz JT, Diener IV, Freiberg K, *et al.* Efficacy of two antiseptic regimens on skin colonization of insertion sites for two different catheter types - a randomized clinical trial. Infection 2016; DOI 10.1007/s15010-016-0899-6

Important user information

octenisept®

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: For repeated, short-term antiseptic treatment of mucous membranes, adjacent skin and as adjuvant antiseptic wound treatment. octenisept® is intended for superficial application and must not be applied e.g. by syringe into the depths of the tissue. Contraindications: octenisept® may not be used in cases of hypersensitivity to any of the components of the preparation. octenisept® should not be used for rinsing the abdominal cavity (e.g. intra-operatively) or the bladder, nor the tympanic membrane. Undesirable effects: rare: burning, redness, itching and warmth at the application site, very rare: allergic contact reaction, e.g. temporary redness at the application site; frequency unknown: after lavage of deep wounds with a syringe, persistent edema, erythema and also tissue necrosis have been reported, in some cases requiring surgical revision . Rinsing of the oral cavity may cause a transitory bitter sensation. Special warnings and special precautions for use: Do not swallow octenisept® and do not allow octenisept® to pass into the circulation, e.g. as a result of accidental injection. Usage of octenisept® in the eye should be avoided. In case of contact with eyes, rinse immediately with plenty of water. If any of the side effects gets serious, or if you notice any side effects not listed in this user information, please tell your doctor or pharmacist.

To prevent possible tissue injury, the product must not be injected into the deep tissue using a syringe. The product is intended for superficial use only (application by swab or spray pump).

Manufacturer:
Schülke & Mayr GmbH, 22840 Norderstedt, Germany, Phone +49 40 52100-0, info@schuelke.com, www.schuelke.com

schülke worldwide:

Australia
Schulke Australia Pty Ltd
Macquarie Park NSW 2113
Phone +61 2 8875 9300
Fax +61 2 8875 9301

Austria
Schülke & Mayr Ges.m.b.H.
1070 Vienna
Phone +43 1 523 25 01 0
Fax +43 1 523 25 01 60

Brazil
Vic Pharma Indústria e Comércio Ltda
Taquaratinga/SP – CEP 15900-000
Phone +16 3253 8100
Fax +16 3253 8101

Czech Republic
Schulke CZ, s.r.o.
73581 Bohumín
Phone +420 558 320 260
Fax +420 558 320 261

France
Schülke France SARL
92257 La Garenne-Colombes
Phone +33 1 42 91 42 42
Fax +33 1 42 91 42 88

India
Schulke India Pvt. Ltd.
Powai, Mumbai – 400076
Phone +91 22 61736600

Japan
Schulke Japan LLC
Shinagawa East One Tower
2-16-1 Konan, Minato-ku, Tokyo
108-0075
Phone +81 3 6894 3335
Fax +81 3 3453 0207

Malaysia
Schülke & Mayr (Asia)
Sdn Bhd.
47301 Petaling Jaya,
Selangor
Phone +60 3 78 85 80 20
Fax +60 3 78 85 80 21

Netherlands
Schülke & Mayr Benelux B.V.
2031 CC Haarlem
Phone +31 23 535 26 34
Fax +31 23 536 79 70

New Zealand
Schulke New Zealand Limited
Auckland 1010
Phone +61 2 8875 9300
Fax +61 2 8875 9301

Poland
Schulke Polska Sp. z o.o.
02-305 Warszawa
Phone +48 22 11 60 700
Fax +48 22 11 60 701

Singapore
Schülke & Mayr (Asia)
Pte. Ltd.
Singapore 159410
Phone +65 62 57 23 88
Fax +65 62 57 93 88

Slovakia
Schulke SK, s.r.o.
97101 Prievidza
Phone +421 46 549 45 87
Fax +420 558 320 261

Switzerland
Schülke & Mayr AG
8003 Zurich
Phone +41 44 466 55 44
Fax +41 44 466 55 33

United Kingdom
Schulke & Mayr UK Ltd.
Sheffield S9 1AT
Phone +44 114 254 35 00
Fax +44 114 254 35 01

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