octenidine 0.5% concentrate

Answers to Frequently Asked Questions - FAQs

1) What are the benefits of using octenidine 0.5% concentrate?

2) What´s the advantage of octenidine 0.5% concentrate?

3) Why should the ready-to-use solution be prepared under sterile conditions?

4) How should the ready-to-use formulation prepared from the octenidine 0.5% concentrate be sterilised?

5) Which packaging is suitable for autoclaving?

6) What should be considered when aseptic filling is carried out through a sterile filter?

7) What information do we provide on the stability of the octenidine 0.5% concentrate?

8) What must be taken into consideration if octenidine 0.5% concentrate shows turbidity or precipitation?

9) Which formulation does schülke recommend? What information is available on the stability of this ready-to-use solution?

10) How can the concentration of octenidine-dihydrochloride in the ready-to-use solution be determined?

11) What exposure times should be observed?

1) What are the benefits of using octenidine 0.5% concentrate?

Octenidine dihydrochloride (octenidine) in a concentration of 0.1 % is recommended in the RKI (Robert Koch Institute, Germany) guideline for the prevention of hospital-acquired infections in neonatal intensive care patients with a birth weight of less than 1500 g as the active substance of choice for skin and mucous membrane antiseptics (*reference: Bundesgesundheitsbl-Gesundheitsforsch-Gesundheitsschutz 2007, 50:1265-1303 Published online: October 5th, 2007 AND Bundesgesundheitsbl. Gesundheitsforsch. Gesundheitsschutz 2018 May;61(5):608-626. doi: 10.1007/s00103-018-2718-y*). schülke offers the octenidine 0.5% concentrate to hospital pharmacists for the preparation of a 0.1% octenidine ready-to-use solution for a quick and practical implementation of this requirement for doctors to increase patient safety. Octenidine 0.5% concentrate is an intermediate product that is manufactured in accordance with GMP and approved by a Qualified Person (QP).

2) What are the advantages of octenidine 0.5% concentrate formulation ?

The formulation is surfactant-free. However, wetting is still ensured by the ambiphilic property of octenidine. Dilution with water to an octenidine content of 0.1% results in a compatible isotonic ready-to-use solution.

The formulation significantly extends the shelf life of the concentrate. The shelf life is 24 months when stored in an unopened container at room temperature.

The product category "intermediate product" reduces the testing effort of the manufacturing pharmacist to identity testing.

3) Why should the ready-to-use solution be prepared under sterile conditions?

This is recommended by schülke for safety during use.

4) How should the ready-to-use formulation prepared from the octenidine 0.5% concentrate be sterilised?

The solution prepared from octenidine 0.5% concentrate can be sterilised by autoclaving or converted into a sterile product by sterile filtration with aseptic filling into pre-sterilised containers. We recommend the standard method of autoclaving at 121°C for 15 minutes in accordance with *Ph. Eur.* in the final container, as this is considered to be the safest method.

5) Which packaging is suitable for autoclaving?

Rinsing solution bottle PP 100ml

Supplier: IphaS Pharma-Verpackungen

Art.-No.: 43048

White PP tamper evident closure with chlorobutyl stopper, order No. 43045

Injection bottle 100ml transparent class 1

Supplier: IphaS Pharma-Verpackungen

order No. 46540

Flare (crimp) cap, order No. 46040

Injection plugs, order No. 45013

6) What should be considered when aseptic filling is carried out through a sterile filter?

octenidine 0.5% concentrate or the ready-to-use solution prepared from it contains octenidine dihydrochloride as the active ingredient. Due to its chemical structure, it is surface-active and can therefore be absorbed on the surfaces of filter materials.

During sterile filtration of the solution, some of the octenidine molecules may be bound to the filter, depending on the sterile filter. The filtrate may therefore have a lower octenidine content than the solution before filtration. Based on our own tests, we can recommend sterile filters with which this does not occur. However, at least 5 ml of ready-to-use solution should be filtered.

We therefore recommend the following sterile filters for sterile filtration:

- syringe filter units Minisart® (sterile):

  supplier: Sartorius
  - Minisart® High Flow Syringe Filter 28mm, Polyethersulfone (PES), pore Size 0.22 µm; order no. 16532----------K
  - Minisart® NML Syringe Filter 28mm, pore Size 0.2 µm; order no. 16534----------K

- recommended packaging material for aseptic filling is:

  supplier: Ursatec Verpackung GmbH
  - Ursatec's 3K System Horizontal Spray 50ml; order no. 08/081/UT

This is a pumping system which, after aseptic filling, guarantees perfect microbiological purity of the finished solution even after opening. The pumps also come with a detailed description and instructions for sterile filling.

All the materials for sterile filtration and packaging mentioned in this document are recommended by schülke to prepare the ready-to-use solution. However, other filters can also be used if necessary, provided that the content of octenidine is determined afterwards by using suitable analytical methods. The release of the 0.1% octenidine ready-to-use solution is the responsibility of the manufacturer in the local institutional/hospital pharmacy.

7) What information do we provide on the stability of the octenidine 0.5% concentrate?

octenidine 0.5% concentrate is stable for 24 months in an unopened container at 15 - 25°C and must not be refrigerated! The expiry date is indicated on the packaging/label. In the case of aseptic collection, the shelf life corresponds to the expiry date stated.. If aseptic sampling is not performed, and therefore microbiological contamination cannot be ruled out, the shelf life of the ready-to-use solution must be shortened by the manufacturer (pharmacist) accordingly.

8) What must be taken into consideration if octenidine 0.5% concentrate shows turbidity and precipitation?

If stored below 15°C, the high concentration of octenidine may cause turbidity and precipitation, so please check if the product is available as a clear solution before processing.

Any turbidity or precipitation is reversible. If this occurs,the product simply needs to be stored at the specified temperatures of 15 - 25°C for approximately 2 hours and shaken several times.

In order to ensure product quality, internal chromatographic tests were carried out which showed that the concentration of active ingredient for the redissolved product were well within the release specification.

9) Which formulation does schülke recommend?
What information regarding stability of ready-to-use solution does master formula provide?

schülke recommends diluting the octenidine 0.5% concentrate with purified water to obtain a ready-to-use solution containing 0.1% octenidine. If diluted with electrolyte-containing solutions, such as Ringer's solution or isotonic saline solution, precipitation may occur.

schülke recommends using only containers that are compatible with the ready-to-use solution and are capable of maintaining the microbiological status. However, prompt use is recommended in any case. The recommended shelf life for the ready-to-use solution is 6 months at room temperature. The manufacturing pharmacist is responsible for the shelf life in the final container.

For containers where aseptic removal is not possible (e.g. bottles with lids, syringes), single use is recommended. Any remaining unused solution should be discarded.

It is therefore advisable to use smaller containers or containers that allow aseptic removal (e.g. infusion bottles or 3K system).

10) How could the concentration of octenidine(-dihydrochloride) in ready-to-use solution be determined?

schülke recommends using UV/Vis spectrometry to determine the octenidine dihydrochloride concentration of the final solution. A corresponding method is available on request.

11) What exposure times should be observed?

Studies on antiseptics on skin with few sebaceous glands have shown that the ready-to-use solution (made of octenidine 0.5% concentrate) has a comparable efficacy to isopropanol (IPA) after 2 minutes. Therefore, the contact (exposure) time should not be shorter than this and the liquid must remain (i.e. not be wiped dry with a cloth) for at least 2 minutes.