



Expert information

CE 0124

HISTOLITH NaOCl 3%

Manufacturer

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Name

HISTOLITH NaOCl 3%
For rinsing of root canals
For dental use only

Composition

1 ml of solution contains 31.5 mg (3.15% m/V) sodium hypochlorite (corresponds to 3.0% m/V active chlorine), sodium chloride, sodium hydroxide and purified water

Indications

For rinsing and cleaning of root canals during root canal preparation

Contra-indications

Allergies to chlorine
Open apical foramen

Side-effects

When used as intended in the root canal, no side effects are known.
If sodium hypochlorite passes through the apex, irritations of the periapical tissue are possible. On healthy tissue, HISTOLITH NaOCl 3% has an irritant effect.

Mode of application

After removing the closing cap attach or connect by turning a suitable disposable syringe onto the ESD-insert of the bottle neck and raise required volume. Subsequent to the positioning of a suitable cannula, rinse the root canal according to the individual rinse protocol.

For application of other rinsing methods, the solution can be taken via the opening for pouring out.

During the preparation of the root canal, the latter is rinsed with HISTOLITH NaOCl 3% by using suitable instruments (e.g. syringe with irrigation cannula, ultrasonic-activated or vibration-activated rinsing device) and with a qualified method (slow application without pressure, removing the rinsing solution by suction, protection of gingiva and oral mucosa by use of rubber dam) each time a new size of instrument is used, until treatment is complete.

Further notice

Sodium hypochlorite has a tissue-dissolving effect in particular on necrotic tissue. In case of an inappropriate application (e.g. pressing the solution through the apex) this may cause damages on vital tissue.

If the root canal is previously rinsed with EDTA-solution for widening the root canal and subsequently purified with HISTOLITH NaOCl 3%, this combination can be used to remove the smear layer during the root canal preparation.

The direct sequential use (without intermediate rinsing) of chlorhexidine and NaOCl solutions should be avoided.

In order to prevent pain and swelling through residues of sodium hypochlorite in the root canal the last rinsing can be done with a physiological saline solution. Do not pour back residues of the solution into the bottle.

Warnings

Caution, irritant.

Avoid contact of sodium hypochlorite solution with mucous membrane, skin and eyes as well as the penetration into the periapical tissue.

The safety data sheet can be downloaded from www.legeartis.de or requested by E-Mail from sicherheitsdatenblaetter@legeartis.de.

Shelf life

Store in upright position, only in the original container.

HISTOLITH NaOCl 3% has a shelf life of 3 years (unopened, storage at 2 - 8 °C).

The period of use after first opening is 6 months.

HISTOLITH NaOCl 3% shall not be used after the expiry date. The container has to be kept tightly closed, as otherwise a decrease of the NaOCl concentration has to be expected.

Administrative form and package sizes

200 ml solution Item number 0032339

500 ml solution Item number 0032340

Date of revision

2020-08

Symbol of "Expiry date"



Symbol of "Batch number"



Symbol of "Pay attention to the directions for use"



Symbol of "Manufacturer"

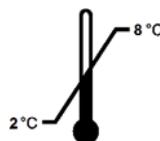


Symbol of "Catalogue number"

Shows Item number of the manufacturer



Symbol of "Temperature limitation"



Symbol of "Medical Device"



1. Handling of the ESD-syringe filling system with Luer or Luer Lock syringe



Remove the cap



Connect the syringe



Withdraw the desired volume



Remove the syringe



Close the cap

2. Pouring out the solution (without syringe) is also possible.