



Package leaflet and summary of product characteristics

HISTOLITH NaOCl 5%

Dental solution (for rinsing of root canals)

1. Name of the medicinal Product

HISTOLITH NaOCl 5%

2. Qualitative and quantitative composition

1 ml of solution contains 52.5 mg (5.25% m/V) sodium hypochlorite corresponding to 50 mg (5.0% m/V) active chlorine

Full list of excipients, see section 6.1

3. Pharmaceutical form

Solution for dental use (for rinsing of root canals)

4. Clinical particulars

4.1 Therapeutic indications

For cleaning and disinfection of root canals

4.2 Posology and method of administration

The quantity of HISTOLITH NaOCl 5% required depends on local given factors. When treating the root canal, it is advisory to rinse with HISTOLITH NaOCl 5% each time a new size of instrument is used.

After each change of the instrument size during preparation the root canal is rinsed out with suitable instruments (e.g. syringe with rinsing cannula, ultrasonic-activated or vibration-activated device) and with a qualified method (slow application without pressure, removing the rinsing solution by suction, protection of gingiva and oral mucosa by using a coffer-dam) until treatment is complete.

If an EDTA-solution is used for widening the root canal first and then the root canal is cleaned with HISTOLITH NaOCl 5% this combination is able to remove the smear layer arising during the preparation of the root canal.

4.3 Contraindications

- Hypersensitivity to the active substance or any other ingredients listed in Section 6.1 or chlorine
- Open apical foramen

4.4 Special warnings and precautions for use

Caution, caustic.

The contact of sodium hypochlorite solution with mucous membranes, skin and eyes should be avoided by appropriate security measures. The overpressure by the rinse solution must be avoided, otherwise they will get into the periapical tissue and can cause serious side effects in some cases (see section 4.8)

4.5 Interactions with other medicinal products and other forms of interactions

There have been no studies on the detection of interactions

4.6 Fertility, pregnancy and lactation

Because of the anticipated low systemic exposure of sodium hypochlorite following topical application of HISTOLITH NaOCl 5% no effect on pregnancy or breastfed newborns/infants of treated women are expected.

HISTOLITH NaOCl 5% can be used during pregnancy and lactating with caution.

For HISTOLITH NaOCl 5% there are no studies on exposed pregnant women available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development (see section 5.3).

4.7 Effects on ability to drive and use machines

HISTOLITH NaOCl 5% has no or negligent influence on the ability to drive and the ability to use machinery

4.8 Undesirable effects

In the assessment of adverse events following frequencies are used:

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1000$ to $< 1/100$)

Rare ($\geq 1/10000$ to $< 1/1000$)

Very rare ($< 1/10000$)

Not known (frequency based on available data cannot be estimated)

On vital tissue HISTOLITH NaOCl 5% effects highly caustic. In case of an inappropriate application (e.g. pressing the solution through the apex) this, because of its tissue-dissolving properties, may cause damages on vital tissue which comes in contact with NaOCl. Mostly, but not in every case, this damages are reversible.

The following side effects have been reported (frequency not known):

- hypersensitivity, including swelling of face or mouth, oedema,
- inflammation, ulceration, necrosis, ecchymosis,
- pain,
- paresthesia and anesthesia affected facial nerves

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after marketing authorisation is of great importance. It allows continuous monitoring of the risk-benefit ratio of medicinal product. Health professionals are encouraged to report any suspect case of an adverse reaction to the Federal Institute for Drugs and Medical Devices, Department of Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de

4.9 Overdose and other dosage mistakes

When using sodium hypochlorite as a dental solution, no cases of over-dose were reported

If acute reactions occur after the canal preparation, the following reasons may be relevant:

- Excessive instrument usage in the apical tissue. As a result, infected tissue is pressed through the apical foramen into the periapical area.
- The use of infected instruments.
- Considerable enlargement of the apical foramen. Tissue irritation from rinsing fluids is exacerbated by this.
- Cytotoxic effect of medication which is pressed through the apical foramen.

Therapy: Application of the coffer-dam and removal of the temporary filling; if necessary enlargement of the canal and repeated rinsing with physiological sodium chloride solution. If necessary treat with anti-inflammatory measures.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Solutions of sodium hypochlorite dissolve organic tissue and have a good anti-bacterial effect. The tissue-dissolving effect, as well as the cytotoxic effect, depends on the concentration of the solution, whereby necrotic tissue is dissolved more easily than vital tissue.

Statistical analyses have shown that concentrated sodium hypochlorite solutions dissolve significantly more necrotic tissue and at a faster rate than weaker solutions.

With regard to toxicity and periapical irritation, no differences were ascertained when compared with physiological sodium chloride solution.

It must be avoided that HISTOLITH NaOCl 5% reaches the periapical tissue above the apical foramen.

To prevent pain and swelling caused by residues of sodium hypochlorite, the final rinse could be conducted with a physiological sodium chloride solution.

5.2 Pharmacokinetic properties

For pharmacokinetics no data are available

5.3 Preclinical safety data

Based on studies of acute toxicity, reproductive toxicity, genotoxicity and of carcinogenic preclinical data no special hazards for humans were perceptible.

Sodium hypochlorite (5%) is cytotoxic in vitro (fibroblasts, Hela cells) and hemolytic (Erythrocytes). After intradermal injection of NaOCl (5.25%) in rats inflammatory reactions and hemorrhage were observed. In guinea pigs no differences in the inflammatory response were observed after 7 - 14 days treatment with NaOCl concentrations of 0.9% up to 8.4% compared to physiologic salt solution. On the rabbit eye both the undiluted (5.25%) and a 10-fold diluted NaOCl solution caused rapid and up to 48h persistent local reactions (hyperemia and edema).

6. Pharmaceutical particulars

6.1 List of excipients

Sodium chloride, sodium hydroxide and purified water

6.2 Incompatibilities

Because of the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. This medicinal product should not be used without prior thorough intermediate irrigation with chlorhexidine solutions or other rinsing solutions.

6.3 Shelf life

3 years (unopened, stored at 2 - 8 °C)

The period of use after first opening the bottle is 6 months

You may not use HISTOLITH NaOCl 5% after the expiry date which is printed on the label and on the package

6.4 Special precautions for storage

Store in upright position, in the original container

The container must be kept tightly closed and stored in the refrigerator at 2 - 8 °C.

6.5 Nature and contents of container

HDPE bottle with 50 ml (Item number 0032111), 200 ml (Item number 0032120) and 500 ml (Item number 0032112) of solution

6.6 Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines, if you no longer need it. These measures are helping to protect the environment. Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

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8. Marketing authorisation number

6030426.00.00

9. Date of renewal of the authorisation

09.06.2005

10. Date of revision of the text

September 2019

11. Deferred sales

Only for sale in pharmacies ("dental use only")

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.