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 arised during the preparation of the root canal.

4.3 Contraindications
Allergies to chlorine; open apical foramen

4.4 Special warnings and precautions for use
Caution, caustic
Avoid the contact of sodium hypochlorite solution with mucous membrane, skin and eyes as well as the penetration into the periapical tissue.

4.5 Interactions with other medicinal products and other forms of interactions
If used as intended none known

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 the pregnancy or the breastfed newborns/infant of treated women are anticipated. 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
No special precautions are required.

4.8 Undesirable effects
In the assessment of adverse events following frequencies are used:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (> 1/1000 - <1/100)
- Rare (≥ 1/10000 - <1/1000)
- Very rare (< 1/10000)

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

On vital tissue, HISTOLITH NaOCl 5% has a caustic effect. Patients are asked to inform their dentist, if they notice any side effects, particular such which are not mentioned in this leaflet.

4.9 Overdose and other dosage mistakes
When using sodium hypochlorite as a dental solution, were no cases of over-dose reported

Acute reactions following canal treatment are rare. If they do occur, the following factors are contributory:
- 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.

Nevertheless, if possible, HISTOLITH NaOCl 5% should not be brought through 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

Do not use with chlorhexidine solution without intermediate rinsing.
Do not mix with other 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

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, 200 ml and 500 ml 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

March 2013

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.