



# Hypochlorit-SPEIKO®

## 5.25 % Dental solution · Sodium hypochlorite 5.25 % (W/W)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your dentist or pharmacist if you need more information or advice.
- If you get any side effects, talk to your dentist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your dentist if you do not feel better or if you feel worse after one day.

### What is in this leaflet

1. What Hypochlorit-SPEIKO is and what it is used for
2. What you need to know before you use Hypochlorit-SPEIKO
3. How to use Hypochlorit-SPEIKO
4. Possible side effects
5. How to store Hypochlorit-SPEIKO
6. Contents of the pack and other information

### 1. What Hypochlorit-SPEIKO is and what it is used for

Hypochlorit-SPEIKO is a product to destroy pathogenic organisms (antiseptic). It is for cleaning and disinfection of root canals.

You must talk to your dentist if you do not feel better or if you feel worse after 1 day.

### 2. What you need to know before you use Hypochlorit-SPEIKO

#### Do not use Hypochlorit-SPEIKO:

- if you are allergic to sodium hypochlorite, chlorine or any of the other ingredients of this medicine (listed in section 6).
- in cases of aperture of the bone at the root tip (open foramen apicale).

### Warnings and precautions

Caution, corrosive!

The contact of sodium hypochlorite solution with mucous membranes, skin and eyes should be avoided by appropriate safety precautions. Overpressing of the rinsing solution must be avoided, since otherwise this may be introduced into the periapical tissue where it may lead to severe side effects (see section 4).

### Other medicines and Hypochlorit-SPEIKO

Tell your dentist or pharmacist if you are taking, have recently taken or might take any other medicines.

This medicine should not be used together with chlorhexidine solution or other rinsing solutions without prior thorough rinsing.

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your dentist or pharmacist for advice before taking this medicine.

There are no known restrictions for the use during pregnancy or during breast-feeding.

### Driving and using machines

Hypochlorit-SPEIKO has no or negligible effect on the ability to drive and use machines.

### 3. How to use Hypochlorit-SPEIKO

Hypochlorit-SPEIKO is exclusively administered by your dentist.

The required amount of Hypochlorit-SPEIKO depends on the local circumstances.

Sodium hypochlorite solution is used to rinse and clean the root canal in the course of root canal treatment by applying adequate instruments and the proper procedure (slow application without exertion of pressure, removal of the rinsing solution, protection of the gum and the oral mucosa by using a protective plastic film (dental dam)) for the rinsing clean-up of the root canal.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Sodium hypochlorite displays strongly etching effects on vital tissues. Incorrect use (e.g. overpressing of the solution beyond the apex) may cause damage of living tissue that comes into contact with the rinsing solution by the tissue-dissolving effect of sodium hypochlorite. In most, but not in all cases, this is reversible.

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

- hypersensitivity reactions, among others swelling of the face or mouth area, oedema
- inflammations, ulcerations, death of tissue (necrosis), small areas of bleeding (ecchymosis)
- pain
- abnormal sensation (paraesthesia) and numbness (anaesthesia) of the affected facial nerves

### Reporting of side effects

If you get any side effects, talk to your dentist or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: [www.bfarm.de](http://www.bfarm.de). By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Hypochlorit-SPEIKO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after „Verwendbar bis“. The expiry date refers to the last day of that month.

### Storage conditions

Store in a refrigerator at 4 °C – 8 °C. Keep the bottle tightly closed in the outer carton in order to protect from light.

After opening, store in a refrigerator at 4 °C – 8 °C.

### Shelf-life after first opening

After the first opening the bottle can be stored for 6 weeks in a refrigerator at 4 °C – 8 °C.

A decrease of the sodium hypochlorite concentration during storage at room temperature after first opening must be anticipated.

Residual amounts of Hypochlorit-SPEIKO can be strongly diluted with water and flushed down the sink. Empty and water-rinsed bottles can be disposed of as regular waste.

### 6. Contents of the pack and further information

#### What Hypochlorit-SPEIKO contains

- The active substance is sodium hypochlorite. 100 ml (equivalent to 110.60 g) contain: sodium hypochlorite solution 6 % (w/w) 83.283 ml (= 96.775 g). Final concentration of sodium hypochlorite = 5.25 % (w/w).
- The other ingredient is purified water.

#### What Hypochlorit-SPEIKO looks like and contents of the pack

Hypochlorit-SPEIKO is a clear, yellowish solution.

Plastic bottle with 30 ml dental solution.

Plastic bottle with 100 ml dental solution.

Not all pack sizes may be marketed.