



# AHL Generic



## NON-AQUEOUS CALCIUM HYDROXIDE PASTE

### DIRECTIONS FOR USE

#### FEATURES:

A ready to use calcium hydroxide paste containing approximately 37.5% by weight calcium hydroxide. It is a smooth, creamy, polyethylene glycol-based preparation designed for easy controlled dispensing during endodontic decontamination. It may be used for temporary pulp capping or lining but not as a base.

#### INTENDED PURPOSE:

Temporary endodontic dressing

#### INTENDED PATIENT POPULATION:

From child to geriatrics

#### INTENDED USER:

This product has been formulated for use in dentistry and is intended for use by dental professionals only.

#### CLINICAL BENEFIT:

To restore the function of the teeth and help maintain the integrity of the remaining tooth structure.

#### INDICATIONS FOR USE:

- Temporary and intermediate endodontic dressing
- Pulp capping

#### CONTRA-INDICATIONS:

- Direct and indirect pulp capping if the pulp damage is irreversible
- Direct pulp capping after exposure of the pulp in carious dentin, if:
  - the area of exposure is larger than 1mm<sup>2</sup>,
  - a completely dry field cannot be established
  - the treatment of the tooth cannot be completed in one appointment
  - the tooth concerned is already causing discomfort.

#### CONTENTS OF PACK:

Syringe 1.5ml, tips, instructions for use

#### PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- Contact of calcium hydroxide with the skin, eyes and mucous membrane may cause local irritation and burns.
- If inadvertent contact occurs, rinse with copious amounts of water and seek medical advice

#### PROCEDURE

##### (1) PLACEMENT:

- Following instrumentation of the root canal, introduce calcium hydroxide paste into the cleaned canal using an appropriate tip attached to the syringe.
- Plastic tips can be trimmed to the required length prior to use.
- Fill canal from bottom up.
- Seal access cavity using an appropriate temporary sealing material.
- In the case of pulp capping or lining, apply a minimal amount of paste to clean affected area only.

#### SINGLE USE



The syringe may only be used once due to hygienic reasons (prevention of cross-contamination between patients).

#### STORAGE:



Store in a cool, dry place (5-25°C).  
Always replace cap immediately after use.

#### EXPIRY:



The expiry date is shown in year, month format. Do not use the product after this date.

#### DISPOSAL:

Dispose of the contents and containers in accordance with relevant local and national requirements.

#### POSSIBLE SIDE EFFECTS / RESIDUAL RISKS:

- This product contains substances that may cause an allergic reaction.

#### BATCH CODE:



The batch code gives an open date of manufacture in month, year, day format with a numerical suffix to uniquely identify the batch of material. Please quote this batch number in all correspondence.

#### DEVICE CODES:



400X1 4 x 1.5ml Syringe

#### COMPOSITION:

Composition	% by weight
Calcium Hydroxide	30 – 40
Radiopacifiers	10 – 20
polyethylene glycol	40 – 50

AHL operate a policy of continuing surveillance & monitoring of our products. If you experience any incidents relating to the use of this product, please immediately contact us at the below address stating the batch number shown on the packaging. If you experience any serious incident relating to the use of this product, please immediately contact AHL at the below address and the competent authority of the territory you are in..

A summary of safety & clinical performance (SSCP) is available via the EUDAMED database. <https://ec.europa.eu/tools/eudamed>

Caution: U.S. Federal Law restricts this device to sale by or on the order of a dental professional.



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