

AHL Generic (Eg

LIGHT CURE CALCIUM HYDROXIDE LINER (POWDER-LIQUID)

DIRECTIONS FOR USE

FEATURES:

A HEMA free light-curing, radiopaque one-component material containing Calcium hydroxide.

INTENDED PURPOSE:

Base or liner under other restorative materials

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:

- · Indirect pulp capping
- Protective liner under dental filling materials, cements and other base materials.

CONTRA-INDICATIONS:

- · Direct pulp capping
- Acetone-containing products are detrimental to calcium hydroxide materials, Minimise contact of these products with calcium hydroxide liners.

CONTENTS OF PACK:

Syringe 4g, single-use tips, instructions for use

PRECAUTIONS AND WARNINGS:

- · Do not expose patients or users known to be allergic to this type of material.
- LC calcium hydroxide liner adheres to methacrylate-based products, e.g. crown and bridge materials, temporary sealing materials and certain impression materials (e.g.polyether), which can lead to removal of the cavity lining.
- In such cases, application of a separating agent is recommended (e.g. Vaseline, glycerine gel etc.).
- Remove the insulating material prior to placement of the final restoration
- Once dispensed, LC liners must not be exposed to direct light (operating light, sunlight) and must be applied as quickly as possible.
- LC calcium hydroxide liner contains methacrylates, BHT and amines thus should not be used in case of known hypersensitivities (allergies) to any of these ingredients.
- Calcium hydroxide has a caustic effect on the skin, eyes, and mucosal tissue.
- In case of accidental contact rinse immediately with plenty of water and seek medical advice.
- In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).
- Phenolic substances, especially products containing eugenol and thymol, impede the curing LC calcium hydroxide liner therefore should be avoided.

PROCEDURE

(1) PREPARATION:

- Prepare cavity in normal way.
- The cavity preparation should be dry.

(2) PLACEMENT:

- Dispense the required amount of calcium hydroxide paste from the syringe onto a mixing pad and apply with a suitable instrument.
- Avoid touching the margins of the cavity.
- Cavity lining with a thickness in excess of 1mm need to be built up in layers with each layer being cured under blue light for at least 20 seconds.
- Remove any excess of material before curing, do not remove excess cured material with a probe but a rotating instrument before applying the restoration according to manufactures instructions.

(3) CURING

- After placing cure with a light unit.
- Select the light curing time in the table below.
- Light cure the entire surface of the restoration.
- For deep cavities, the layering technique is recommended, Place in a layer of up to 2mm depth and cure with a dental light cure unit.

Light Curing Unit	LED curing unit	Halogen lamp curing unit
Light Curing Time	10 seconds	20 seconds
Wavelength	440-490 nm	400-500 nm
Light Intensity	≥ 1000 mW/cm ²	≥ 500 mW/cm ²

- Use a dental light-curing unit having specifications equivalent to those described above.
- When using a unit having performance other than these recommendations, follow the instructions for that unit

(4) FINISHING:

 After light curing the material should be hard enough to have restoration placed over the top.

SINGLE USE



Discard the tip after use.

This must not be re-used on another patient for hygienic reasons.

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 and allergic reaction.

BATCH CODE:

LOT

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:

COMPOSITION

414X1

REF

4g syringe

 Composition
 % by weight

 Methacrylate resins
 60 – 80

 Inert fillers
 20 – 30

 Calcium Hydroxide
 1 – 10

 Stabiliser
 <1</td>

 Activators
 <1</td>

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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