



AHL Generic



CALCIUM HYDROXIDE BASE LINER

DIRECTIONS FOR USE

FEATURES:

A rigid, self-setting, radiopaque composition that will not inhibit the polymerisation of acrylic and composite restorations.

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:

- Direct and indirect pulp capping.
- Protective liner under dental filling materials, cements and other base materials.

CONTRA-INDICATIONS:

- Hypersensitivity against sulphonamides or other components, respectively of the product.
- Acetone-containing products are detrimental to calcium hydroxide materials.
- Minimise contact of these products with calcium hydroxide liners.

CONTENTS OF PACK:

Base paste 13g, catalyst paste 11g, mixing pad, instructions for use

PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- May cause allergic reactions in persons susceptible to sulphonamides.
- Contains calcium hydroxide.
- Contains 1,3-Butylene Glycol Disalicylate.
- Irritating to skin and eyes.
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- In case of contact with skin, wash immediately with plenty of soap and water.
- In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

PROCEDURE

(1) MIXING:

- Extrude equal volumes of the base and catalyst paste onto a mixing pad.
- Mix immediately using a spatula until a uniform colour is achieved.
- DO NOT OVER SPATULATE.
- Mix at 22-24°C.
- To provide maximum working time, complete mixing of the two pastes within 10 seconds.

Total mixing time: 10 seconds.

Setting time: 4 minutes from placement in the oral cavity.

Increased humidity and elevated temperature will reduce available work time and set time. Conversely, decreased humidity and lower temperature will increase available work time and set time.

(2) PLACEMENT:

- Quickly apply the mixed material into the cavity for efficient placement before setting starts.
- The cavity preparation should be dry.
- Avoid touching the margins of the cavity.
- Avoid placing a large bulk of material.
- Remove any excess set material from retention areas or margins with a sharp spoon excavator or bur.

STORAGE:



Store in a cool, dry place (5-25°C).

Always replace cap immediately after use.

It is important to keep tubes tightly sealed when not in use.

Separation of solid and liquid phases of the base paste is accelerated at elevated temperatures. When stored at reduced temperatures, allow the material to return to normal room temperature before using.

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.
- Irritating to skin and eyes.

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:



396X1

13g Base Paste / 11g Catalyst Paste

COMPOSITION:

Composition	% by weight
Butanediol Salicylate Diester	20 – 30
Calcium Hydroxide	20 – 30
Solvent	10 – 20
Catalysts	10 – 50
Radiopacifiers	10 – 15
Pigments	5 – 10

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 above address stating the batch number shown on the packaging.

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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