

# CALULTRA

## CALCIUM HYDROXIDE CAVITY LINER



**Product Description:** Calutra is a two-component, rigid-setting, self curing calcium hydroxide preparation designed for use as a direct and indirect pulp capping agent, and a protective liner under dental filling materials, cements and other base materials in permanent and deciduous dentition.

**Composition:**

**Base:** Calcium hydroxide, N-ethyl O/P toluene sulphonamide, Zinc Oxide and thickening agents  
**Catalyst:** Ethylene glycol salicylate, Zinc Oxide, Radiopacifiers, coloring agents and thickening agents  
**Intended Purpose/Intended Use:** A calcium hydroxide cavity liner as pulp protectant.

**Indications for Use :**

- Used as a direct pulp capping agent when applied to exposed, vital pulp tissue.
- Indirect pulp capping : Applied as a protective barrier between restorative materials and deep vital dentin.

**Instructions for Use:**

**1.Direct Pulp Capping :** Under rubber dam isolation, complete cavity preparation. Rinse the site with sodium hypochlorite 1%. Bleeding may be controlled with a cotton pellet moistened with sterile saline. Gently dry preparation with cotton pellet. Avoid desiccation.

**Manual Mix Tubes:** Dispense equal volumes of base & catalyst pastes on the mixing pad in 1:1 ratio volume. Replace container caps. Mix thoroughly until a uniform color is achieved. Do not over-spatulate. Complete mixing within 10 seconds. Using the long shank ball pointed applicator or similar instrument, place the mix directly on the exposed pulp. The mixed material will set in approximately 2-3 minutes. Setting time might be shorter in the mouth due to moisture and temperature. Remove any set excess from retention areas, enamel, and/or margins with a sharp spoon excavator or a bur. Place desired adhesive, base, and/or restoration following manufacturer's directions. Avoid placing a large bulk of material. The material thickness should be approximately 0.8mm to 1mm. Assess the pulp vitality status at regular intervals approximately 3 to 6 months.

**Manual Mix Syringes:** Remove the cap & install applicator tips to the syringes. Dispense equal volumes of base & catalyst pastes on the mixing pad in 1:1 ratio volume. Replace container caps. Mix thoroughly until a uniform color is achieved. Do not over-spatulate. Complete mixing within 10 seconds. Using the long shank ball pointed applicator or similar instrument, place the mix directly on the exposed pulp. The mixed material will set in approximately 2-3 minutes. Setting time might be shorter in the mouth due to moisture and temperature. Remove any set excess from retention areas, enamel, and/or margins with a sharp spoon excavator or a bur. Place desired adhesive, base, and/or restoration following manufacturer's directions. Avoid placing a large bulk of material. The material thickness should be approximately 0.8mm to 1mm. Assess the pulp vitality status at regular intervals approximately 3 to 6 months.

**Instructions for Use for Cartridge of CalUltra: Automix Cartridge:** Attach the mixing tips to the Automix cartridge, press the plunger of the cartridge to express a homogeneously mixed paste.

**Manual Mix Cartridge:** Activate the plunger of the manual mix cartridge to dispense both base and catalyst paste to a ratio of 1:1 volume on a mixing pad and use spatula to mix the paste for 10 seconds for obtaining homogenous consistency. Use the ball point applicator on suitable instrument to place the material on to the site of application.

**2. Indirect Pulp Capping :** Under suitable isolation, complete cavity preparation and caries removal. Wash cavity thoroughly with water spray and air dry. Dispense and mix Calutra components as outlined earlier. Apply mixed material to desired dentin surfaces. Following completion of set remove any set excess from retention areas, enamel, and/or margins with a sharp spoon excavator or a bur. Complete restoration per restorative material manufacturer's directions for use.

**Warnings :** Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take internally contact with the skin may cause irritation and hypersensitivity. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician. It should not be used with patients who have a history of severe allergic reaction to any of the components.

**Precautions :**

- This product is intended to be used as specifically outlined in the directions for use. Any use of this product inconsistent with the instructions for use is at the discretion and sole responsibility of the practitioner.
- Wear suitable protective clothing, eyewear & gloves.
- The solubility and essentially basic nature of Calutra composition requires that it be used only in situations where it can be protected adequately from the intraoral environment. After the Calutra has completely set cover with restorative material as per manufacturer's directions. Do not leave it exposed to oral environment.
- To achieve good results, use of a rubber dam or adequate isolation is recommended.
- Pulpal hemorrhage must be controlled prior to the application.
- Calutra should be mixed in equal volumes for optimum performance. The mixed material should be homogenous and streak free prior to application.
- Increased humidity and elevated temperature will reduce available work time and set time.
- Containers should be tightly closed immediately after use.
- Store with original caps tightly closed in a well ventilated place at or below room temperature not exceeding 24°C. Refrigerated storage is acceptable when not in use. Allow material to reach room temperature prior to use. Protect from moisture. Do not Freeze. Do not use after expiration date. CalUltra is a multiple dose container (Tube/Cartridge). Opening and closing of the container does not affect the shelf life of the device. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused. Do not interchange base and catalyst tubes caps.

**Contraindications :** Calutra is contraindicated for use in patients with known allergies to any other if its components.

**Storage Conditions :** Store at temperature between 10°C to 24°C (50 °F to 75 °F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

**Shelf Life :** 3 years from the date of manufacturing.

**Presentation:**

**Ref: 40046**  
 Net Content (Tube/Tube) : 24g ,1 x Base Paste, 1 x Catalyst Paste, 1 x Mixing Pad

**Ref: 40059**  
 Net Content : 20g ,1 x Automix Cartridge, 20 x Mixing Tips, 1 x Instruction Manual

**Ref: 40060**  
 Net Content : 15g ,1 x Manual Mix Cartridge (Base & Catalyst), 1 x Mixing Spatula, 1 x Mixing Pad, 1 x Instruction Manual

**Ref: 40064**  
 Net Content (Syringe/Syringe) : 24g ,1 x Base Paste, 1 x Catalyst Paste, 1 x Mixing Pad, 5 x Applicator Tips  
**Disposal conditions :** To be disposed off based on the prevailing rules of the country in which it is used.

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**CE**  
**0123**  
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**UDI** Symbol for "UNIQUE DEVICE IDENTIFIER"  
**LOT** Symbol for "BATCH CODE" **USE-BY DATE** Symbol for "USE-BY DATE" **NON STERILE** Symbol for "NON STERILE" **KEEP DRY** Symbol for "KEEP DRY"  
**CAUTION** Symbol for "CAUTION" **CONSULT INSTRUCTION FOR USE** Symbol for "CONSULT INSTRUCTION FOR USE" **REF** Symbol for "CATALOGUE NUMBER"  
**EC REP** Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"  
**KEEP OUT OF THE REACH OF CHILDREN** Symbol for "KEEP OUT OF THE REACH OF CHILDREN" **MANUFACTURER** Symbol for "MANUFACTURER" **DO NOT USE IF PACKAGE IS DAMAGE** Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"  
**TEMPERATURE LIMIT** Symbol for "TEMPERATURE LIMIT" **KEEP AWAY FROM SUNLIGHT** Symbol for "KEEP AWAY FROM SUNLIGHT" **MD** Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.