

CALULTRA

CALCIUM HYDROXIDE CAVITY LINER

PREVESTDenPro®
THE FUTURE OF DENTISTRY

Product Description: Calultra 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 :

1. Used as a direct pulp capping agent when applied to exposed, vital pulp tissue.
2. 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. Re-place container caps. Mix thoroughly until a uniform color is achieved. Do not over-spatulate. Complete mixing within 10 seconds. Using the bait 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. Assess the pulp vitality at regular intervals.

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 homogenously 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 bait 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 Calultra 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 :

1. 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.
2. Wear suitable protective clothing, eyewear & gloves.
3. The solubility and essentially basic nature of Calultra composition requires that it be used only in situations where it can be protected adequately from the intraoral environment. After the Calultra has completely set cover with restorative material as per manufacturer's directions. Do not leave it exposed to oral environment.
4. To achieve good results, use of a rubber dam or adequate isolation is recommended.
5. Pulpal hemorrhage must be controlled prior to the application.
6. Calultra should be mixed in equal volumes for optimum performance. The mixed material should be homogenous and streak free prior to application.
7. Increased humidity and elevated temperature will reduce available work time and set time.
8. Containers should be tightly closed immediately after use.
9. 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 : Calultra 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 : 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

Disposal conditions : To be disposed off based on the prevailing rules of the country in which it is used.

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"

Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE" **REF** Symbol for "CATALOGUE NUMBER"

ECI/REP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER" Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"

Symbol for "TEMPERATURE LIMIT" 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.