



DESCRIPTION: DSI ApexPaste Hard 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, Zinc Stearate, and thickening agents. **Catalyst:** Ethylene glycol salicylate, β -Tricalcium phosphate, Zinc Oxide, Barium sulphate, Titanium dioxide, Zinc Stearate, coloring agents, and thickening agents.

PURPOSE: A calcium hydroxide cavity liner as pulp protectant.

INDICATIONS:

- 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

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 a cotton pellet. Avoid desiccation. Dispense equal volumes of base and catalyst pastes on the paper pad provided. Replace container caps. Mix thoroughly until a uniform color is achieved. Do not over-spatulate. Complete mixing within 10 sec. 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 min. 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 the manufacturer's directions. Assess the pulp vitality at regular intervals.

Indirect Pulp Capping, Liner: Under suitable isolation, complete cavity preparation and caries removal. Wash the cavity thoroughly with water spray and air dry. Dispense and mix ApexPaste Hard components as outlined earlier. Apply mixed material to desired dentin surfaces. Following completion of the 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 internal 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 reactions 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 ApexPaste Hard composition require that it be used only in situations where it can be protected adequately from the intraoral environment. After the ApexPaste Hard has completely set the cover with restorative material as per the manufacturer's directions. Do not leave it exposed to an oral environment.
- To achieve good results, the use of a rubber dam or adequate isolation is recommended.
- Pulpal hemorrhage must be controlled prior to the application.
- ApexPaste Hard 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 it after the expiration date. ApexPaste Hard is a multiple-dose container (Tube/Tube). Opening and closing the container do not affect the shelf life of the device. The dispensed material shall not be placed back in the container and the dose once applied and used shall not be reused. Do not interchange base and catalyst tube caps.

CONTRAINDICATIONS: ApexPaste Hard is contraindicated for use in patients with known allergies to any other of its components.

STORAGE: Store at a temperature between 10°C (50°F) to 24°C (75°F). Close the cap carefully after use. Keep away from moisture. Shelf life is not affected after opening if stored in a cool dry place. **Shelf life:** 3 Years from the date of manufacturing.

PACKAGING: 1 x Base 12g Paste, 1 x Catalyst 12g Paste, 1 x Mixing Pad.

Ref: APEX-H

SYMBOLS



Consult instructions for use



Medical Device



Caution, consult accompanying documents



Use by Prescription only



Temperature limit



Manufacturer



Keep away from sunlight



Catalogue number



Keep dry



Batch code



Non-sterile product



Use by Date



Do not use if package is damage



Date of Manufacture



Keep Out of Reach of Children

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material. The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.