

Instructions For Use

Caution: US federal law restricts this product for sale by or on order of a dentist or physician.

Product Description: ActaCal PASTE is a creamy ready to-use calcium hydroxide paste with a pH above 11. It is sold in a syringe with accompanying applicator tips.

Composition: Paste contains calcium hydroxide, demineralized water, barium sulfate, polyethylene glycol, and hydroxypropyl methoxycellulose

Intended Use: It is intended to be used as a pulp capping material.

Indications for Use: ActaCal PASTE is a calcium hydroxide paste that has a creamy consistency and is suitable for several indications including:

1. Indirect pulp capping or management of deep caries lesions, or
2. Direct pulp capping

Instructions for Use:

Direct and Indirect Pulp Capping: Can be applied directly using the provided applicator tips. Alternately, small amounts of paste can be dispensed onto the mixing pad. Following this, ActaCal PASTE is applied to the exposed pulp or dentin near the pulp in thin layers and small patches using a suitable instrument. Subsequently, the surface is sealed with a layer of cavity lining material. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

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 the 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: Recommend the use of rubber-dam while working with the product. Use gloves, protective glasses and protective clothing.

Contraindications:

Direct pulp capping after exposure of pulp in carious dentine should not be performed if

1. The areas of exposure is more than 1 square millimeter
2. The treatment cannot be completed in a single sitting
3. A complete dry field cannot be achieved
4. The pulp is irreversibly inflamed

ActaCal should not be used in patients with known allergy of the ingredients listed.

Storage Conditions: Store at temperature between 10°C(50°F) to 24°C(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.

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

engineered
endodontics®