

IFU Size : 161 H x 104 W

CALCIGEL

ALL PURPOSE CALCIUM HYDROXIDE PASTE



Product Description : Ready to use radiopaque, pre-mixed, calcium hydroxide paste with barium sulphate. Calcigel is a creamy paste used as a pulp capping agent or as a temporary dressing. Owing to its high alkalinity (pH12), Calcium Hydroxide neutralize the free acids of the obturating cements and of the restorative materials. It reduces the hypersensitivity of the dentine and helps the neoformation of secondary dentine.

Composition : Paste contains Calcium Hydroxide, Barium Sulphate, Methyl cellulose and purified water.

Intended purpose/Intended use : It is intended to be used as a pulp capping agent liner or as a temporary dressing.

Indications for use : As a liner for pulp capping on vital pulp. Capping after pulpotomy. Cavity Lining before filling Root canal treatment and periapical therapy.

Instructions for use : Attach a disposable applicator to the syringe. Apply a small amount of Calcigel to the clean, affected area. Allow to dry before restoration. 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, burns of 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 : Recommended the use of rubber-dam while working with the product. Use gloves, protective glasses and protective clothing.

Contraindications : Do not use Calcigel for patients with hypersensitivity to the product's components.

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.

Presentation :

Ref : 40007

Trial Pack : 1 x 2g Syringe, 5 x Applicator Tips.

Ref : 40007-1

Intro Pack : 1 x 3g Syringe, 10 x Applicator Tips.

Ref : 40007-2

Regular Pack : 1 x 2.2g Syringe, 20 x Applicator Tips.

Ref : 40008

Economy Pack : 4 x 2g Syringes, 20 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
Issue/Revision : 01/02
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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"
DO NOT USE IF PACKAGE IS DAMAGED Symbol for "DO NOT USE IF PACKAGE IS DAMAGED" **KEEP OUT OF THE REACH OF CHILDREN** Symbol for "KEEP OUT OF THE REACH OF CHILDREN" **MANUFACTURER** Symbol for "MANUFACTURER"
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.