

IFU Size : 161 H x 104 W

CALPLUS

CALCIUM HYDROXIDE PASTE WITH IODOFORM



Product Description : This is premixed oil based calcium hydroxide paste containing iodoform. The addition of iodoform to calcium hydroxide improves radio-opacity and improves disinfecting property of the paste. Non Hardening paste, solubilized calcium hydroxide remains active in root canal for a longer time.

Composition : Calcium Hydroxide, Iodoform, Silicon Oil.

Intended Purpose / Intended Use: It is used as a temporary or permanent root canal filling material. The device is used for all ages above 6 years.

Intended User: Dental Professionals.

Indications for use : ♦ Disinfects canals ♦ Prevents bacterial growth ♦ Promotes periapical healing ♦ Stimulates apexification and apexogenesis ♦ Temporary or Permanent filling material for infected root canals ♦ Treatment of root resorption.

Instructions for use : After root canal preparation, clean and dry root canal. Attach disposable needle to the syringe and check the flow of paste through the needle. Insert needle into the canal, about 2mm short of the apex. Fill canal completely by pushing the plunger while slowly withdrawing the syringe. Clean excess paste with a sterile cotton pellet. Calplus is packaged in a multiple dose container (Syringe). 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.

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 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. If acts irritating to the mucous membrane of the oral cavity, rinse immediately with copious amount of water.
2. Necessary use of rubber dam while working with the product use gloves, protective glasses and protective clothing.
3. Careful manipulation is necessary to ensure excessive material is not extruded through the apex.

Contraindications: Do not use in patient, if allergic to any of its 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 is not affected after opening if stored in a cool dry place.

Shelf Life : 3 years from the date of manufacturing.

Presentation :

Ref: 40005

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

Ref: 40005-1

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

Ref: 40006

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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Issue/Revision : 01/05
Date : 28-10-2025

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"

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

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

🌡 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.