

## CALX-O (Instruction For Use)

(Root Canal Filling Material)(For Root Dressing)

### INTENDED USE:

To be used as a root canal dressing and filling material during endodontic treatment of teeth and as a temporary filling material for pulp capping and pulpotomies

### COMPOSITION:

Calcium Hydroxide, Barium Sulphate & Propylene Glycol

### PRODUCT DESCRIPTION & PROPERTIES:

It is a water based white paste consisting of premixed Calcium Hydroxide and Barium Sulphate. Supplied in a multi dose syringe with disposable pre-bent cannulas for dispensing. Used fill the root canals temporarily during endodontic treatments, the calcium hydroxide provides the induction effect for hard tissue induction and deposition. Barium Sulphate provides radio-opacity aiding in visualisation of the filling material on radiographs. Can be used as a root canal dressing material during endodontic treatment of weeping canals. It can also be used as a temporary filling material during pulp capping and pulpotomies. It can also be used as a temporary root canal filling material for apexogenesis or apexification following pulpotomy.

### INDICATIONS:

- Temporary Root canal filling or dressing material during endodontic treatment.
  - As a temporary filling material during pulp capping, lining, pulpotomies.
  - As a temporary filling or dressing material during apexification in endodontic procedures.
- ### ADVANTAGES:
- Non setting paste water-based paste.
  - Easy handling and easy direct application at the intended site.
  - Ideal for temporary filling of root canal and during pulpectomy.
  - Excellent radiopacity.
  - Premixed, ready to use paste.
  - Syringe type for easy delivery of the paste directly into the canal.

### METHOD OF USE:

- Isolate the teeth using rubber dam, prepare the access cavity and extricate the pulp to the desired extent.
- After the preparation of root canals/tooth cavity, clean and dry the cavity.
- Attach disposable pre-bent cannula to the Calx-O syringe and check the flow of paste through the cannula.
- Insert the tip of the cannula into the dried canal/tooth cavity, about 2-3 mm short of the apex, or above the level of the retained pulp tissue.
- Fill the root canal completely with Calx-O by pushing the syringe plunger slowly and simultaneously withdrawing the tip of the cannula from the canal.
- To ensure the penetration or spread of the material up to the tip of the canal use a spreader of desired size. Care should be taken not to push the material beyond the confinements of root canal, or to damage the retained pulp tissue.

- Clean excess paste from the pulp chamber.
- During pulp capping and pulpotomy procedures apply the calx-o paste as a lining to the retained pulp tissue surface.
- Seal the prepared cavity, ensuring proper coronal seal to prevent contamination from external oral fluids.
- Discard the used cannula tip as per the local regulatory norms. Secure the syringe opening with the cap provided.

### CAUTION / WARNING:

- Do not overfill beyond the apex.
- Avoid direct exposure to sunlight.
- Keep the syringe capped all the time.
- Discard the used cannula tips as per the local regulations.
- Store in a cool and dry area (10°C to 30°C). Improper storage can cause dryness.

### PRECAUTIONS:

- Avoid contact with skin, mucosa and eyes
- Avoid inhalation.
- Do not consume or take internally
- Contact with the skin may cause irritation or hypersensitivity.
- If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water.
- If contact with eyes occurs immediately flush with running water and get medical attention immediately.
- Consult a physician in case of any hypersensitivity reaction.

### CONTRAINDICATIONS:

It should not be used with patients with a history of allergic reaction to any of the components. Should not be used beyond the confinements of root canal and teeth.

### INTERACTIONS WITH OTHER DENTAL MATERIALS:

No such Reactions Noted. Kindly communicate and inform manufacturer in details of any instance.

### ADVERSE REACTIONS :

No such Reactions Noted. Kindly communicate and inform manufacturer in details of any instance.

### PACKAGING:

Multi dose plastic dispensing syringe, packaged with disposable applicator tips.

### STORAGE:

Store in a cool and dry environment. Always close the cap immediately after use to prevent contamination.

### SHELF LIFE:

2 years from the date of manufacturing.

### DISPOSAL CONDITIONS:

Dispose in accordance with local, state and federal environmental regulations.

**This product is specially formulated for use in dentistry and to be used by qualified dental personnel only.**

**Shiva Products**














Mfg. site: B/18, Dwarka Ind. Estate, Naik Pada, Vasai, Vasai (E), Thane – 401 208, Maharashtra, INDIA.  
 Website: www.maarcidental.com  
 Email ID: care@shivaproducts.net  
 Customer Care: +919967806543

**EC REP**  
**Obelis S.A**  
**Boulevard General Wahis 73**  
**1030 Brussels, Belgium**  
 Tel: +(32) 2 732 59 54, Fax: +(32) 2 732 60 03  
 E-mail: mail@obelis.net

**CE**  
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These instructions for use should be kept for the duration of product use.

-  Symbol for "BATCH CODE"  
  Symbol for "USE BY"  
  Symbol for "NON STERILE"  
  Symbol for "KEEP DRY"
-  Symbol for "CAUTION"  
  Symbol for "CONSULT INSTRUCTION FOR USE"  
  Symbol for "CATALOGUE NUMBER"
-  Symbol for "EUROPEAN COMMUNITY AUTHORIZED REPRESENTATIVE"  
  Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"
-  Symbol for "KEEP OUT OF THE REACH OF CHILDREN"  
  Symbol for "MANUFACTURER NAME & ADDRESS"
-  Symbol for "TEMPERATURE LIMITATION"  
  Symbol for "KEEP AWAY FROM SUNLIGHT"

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.