

IFU Size : 161 H x 104 W

ZICAL *Ultra*

ROOT CANAL SEALER

(Automix / Manual Mix Cartridge)

PREVESTDenPro®
THE FUTURE OF DENTISTRY

Product description : Zical ultra Root Canal Sealer is a ZOE based sealer in paste-paste form for permanent filling dental root canals. This sealant has been specially designed to tightly seal the apex of the root and the prepared root canal. It can be easily removed along with Gutta Percha Point when refilling is necessary. Zical ultra is radiopaque, non staining, non irritating with excellent thermal insulation. Its long working time and lubricating qualities are additional features. Low zinc oxide contents of the composition alleviate some of the cytotoxic and inflammatory effects of the tissues.

Composition : Base : Zinc oxide, Radiopacifiers, Preservative and Excipients.

Catalyst : Eugenol, Thickening Agent and Accelerators.

Intended Purpose / Intended Use : It is used as a sealer for permanent filling of root canals.

Indications for Use : Permanent filling material for root canal sealing using Gutta Percha points.

Instructions for Use : In **Manual Mix Cartridge** the root canal should be thoroughly clean and dry before filling. Extrude small amount of pastes on mixing pad and mix thoroughly with spatula for 30 seconds to obtain a homogeneous paste. In case of a **Automix Cartridge**, attach the Mixing Tip to the device before activating the plunger. Introduce the paste into the prepared canal with a suitable root canal instrument. Wet the Guttapercha (GP) Point with the paste and insert the wet Guttapercha (GP) Point into the Canal. Remove excess GP Point and seal the coronal end with base sealer. Net setting time is 45-60 minutes. Zical Ultra is packaged in a multiple dose container (Paste/Paste). 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 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 :

1. This product is intended to be used as specifically outlined in the Instructions for Use. Any use of this product inconsistent with the Instructions for use is at the discretion and sole responsibility of the practitioner.
2. Wear suitable protective clothing, eyewear, and gloves.
3. The solubility and essentially basic nature of Zical Ultra composition requires that it is used only in situations where it can be protected adequately from the intraoral environment.
4. To achieve good results, use of a rubber dam or adequate isolation is recommended.
5. Do not overfill the root canals with the paste.
6. Zical Ultra should be mixed in equal volumes for optimum performance. The mixed material should be homogeneous and streak free prior to application.
7. Increased humidity and elevated temperature will reduce available work time and set time.
8. Containers should be tightly closed immediately after use.
9. Store with original caps tightly closed in a well ventilated place at or below room temperature not exceeding 24°C(75°F). 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 after expiration date.

Contraindications : Do not use Zical Ultra in patients with known allergy to any of the product ingredients.

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 : 40043

Auto Mix Pack : 1 x 15g Automix Cartridge, 20 x Automix Tips.

Ref : 40042

Manual Mix Pack : 1 x 15g Cartridge, Base & Catalyst Paste, 1 x Mixing Pad, 1 x Spatula

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

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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"
EC 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.