

IFU Size : 161 H x 104 W

ENDOSEAL

ROOT CANAL OBTURATION CEMENT



Product Description : Endoseal is a radiopaque, non-resorbable, Zinc Oxide-Eugenol based root canal sealer.

Composition :

Powder Contains : Zinc Oxide, Barium Sulphate, Accelerators, Preservative.

Liquid Contains : Eugenol & Excipients.

Intended Purpose / Intended Use : It is used as permanent root canal filling material.

Indications for Use : Root canal filling and sealing in association with a gutta percha point.

Instructions for Use : Mix carefully for approximately 45-60 seconds, one scoop of powder and 3 - 5 drops of liquid to obtain smooth and homogenous mix, which can easily be introduced into the canal. 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 : Do not use Endoseal with patients that have a history of allergic reaction to Iodine compounds. Avoids contact with eyes.

Contraindications: Do not use in patients with a known allergy 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 not affected after opening if stored in a cool dry place.

Shelf life :

3 years from the date of manufacturing.

Presentation :

Ref : 40031

15g Powder, 10ml Liquid, 1 x Dispensing Dropper, 1 x Spoon and 1 x Mixing Pad.

Ref : 40031-1

20g Powder, 10ml Liquid, 1 x Dispensing Dropper, 1 x Spoon and 1 x Mixing Pad.

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 : 01/04
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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, complaint and reporting of unexpected events contact customer care.