INSTRUCTION FOR USE

PrevaPack

(Root Canal Obturation Cement)

PrevaPack is a radiopaque, non-resorbable root canal sealer based on Zinc Oxide Eugenol (ZOE) chemistry. It is well tolerated by periapical tissues and demonstrates anti-inflammatory properties. When used in conjunction with gutta-percha or silver points, it provides excellent sealing ability and supports long-term obturation of the root canal system.

COMPOSITION

Powder: Dexamethasone , Zinc Oxide, Barium Sulphate, Thymol Iodide, Magnesium Stearate

Liquid: Eugenol, Pharmaceutical-grade excipients

INDICATIONS

- Permanent obturation of root canals.
- Use in combination with gutta-percha points or silver points during root canal therapy.

CONTRAINDICATIONS

- In patients with known hypersensitivity to eugenol, zinc oxide, or any component of the formulation
- In patients with known sensitivity to corticosteroids including dexamethasone
- Not recommended for use in primary (deciduous) teeth where resorbable materials are indicated.

WARNINGS

- Avoid direct contact with eyes, skin, and oral soft tissues
- Eugenol-containing materials may cause irritation or hypersensitivity reactions in susceptible individuals
- Avoid excessive extrusion of material beyond the root apex
- Do not ingest the product
- Keep out of reach of children

In case of accidental exposure:

Skin contact:

- Remove material immediately using cotton or gauze soaked with alcohol and wash thoroughly with soap and water.

Eye contact:

- Flush immediately with copious amounts of clean water and seek medical attention.

If irritation, sensitization, or allergic reactions occur, discontinue use and seek medical advice.

PRECAUTIONS

- Product intended for professional dental use only
- Wear appropriate personal protective equipment including gloves, masks, and protective eyewear during use
- Use rubber dam isolation whenever possible
- Ensure complete cleaning, shaping, and drying of the root canal prior to application
- Use only the amount required for the procedure
- Avoid overfilling and excessive extrusion beyond the apex

ADVERSE REACTIONS

- Possible adverse reactions may include:
- Local tissue irritation
- Hypersensitivity reactions
- Temporary discomfort due to accidental tissue contact

DIRECTIONS FOR USE

1. Clean, shape, and dry the root canal according to standard endodontic procedures.
2. Dispense one measuring scoop of powder and four drops of liquid onto the supplied mixing pad.
3. Using a clean metal or plastic spatula, mix for approximately 50–60 seconds until a uniform, smooth, thick consistency is obtained.
4. Introduce the mixed sealer into the root canal using a suitable lentulo spiral, sealer applicator, or by coating the gutta-percha or silver point prior to insertion.
5. Insert the obturation material and ensure complete filling of the canal space.
6. Verify obturation according to standard clinical procedures.
7. Allow the material to set.

Setting Time:

- Approximately 45–60 minutes from the start of mixing under normal ambient conditions.

PRESENTATION

Ref. No.: PL-0217- PrevaPack- 1 × 15 g Powder Bottle, 1 × 10 ml Liquid Bottle, 1 × Measuring Spoon, 1 × Mixing Pad

STORAGE CONDITIONS

- Store between 10°C and 24°C
- Keep containers tightly closed after each use
- Store in a cool and dry place
- Protect from moisture and direct sunlight
- Shelf life remains unaffected after opening when stored according to instructions
- Do not use after expiry date

SHELF LIFE

3 years from the date of manufacture

DISPOSAL

Dispose of unused product, packaging materials, and contaminated waste according to applicable local regulations and environmental requirements for medical or hazardous waste.

CONTACT

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Failure to comply with the specified storage conditions may alter the working characteristics of the material and reduce its shelf life.
The manufacturer is not responsible for any loss of quality resulting from non-compliance with the specified conditions for transportation, storage, and use of this product. The user assumes full responsibility for using the material for any purposes other than those specified by the manufacturer.
This material is intended solely for professional dental use. Application must be carried out strictly according to the instructions for use. The manufacturer accepts no liability for damages resulting from failure to follow the provided instructions or for use beyond the stipulated applications. The user is responsible for assessing the material's suitability for any purpose not explicitly stated in this instruction sheet. The descriptions and data provided do not constitute a warranty of attributes and are not legally binding.

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

Symbol for "TEMPERATURE LIMITATION"
Symbol for "KEEP DRY"
Symbol for "KEEP OUT OF THE REACH OF CHILDREN"
Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"
Symbol for "KEEP AWAY FROM SUNLIGHT"
Symbol for "CAUTION"
Symbol for "MANUFACTURER NAME & ADDRESS"
Symbol for "CONSULT INSTRUCTION FOR USE"
REF Symbol for "CATALOGUE NUMBER"
Symbol for "USE BY"
MD Symbol for "MEDICAL DEVICE"
Symbol for "NON STERILE"
LOT Symbol for "BATCH CODE"

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