ORATEMP NE

NON - EUGENOL TEMPORARY LUTING CEMENT

PREVESTDenPro®
THE FUTURE OF DENTISTRY

Product Description : Temporary, radiopaque eugenol-free self curing luting cement based on zinc oxide and resin. OraTemp NE suitable for various applications such as cementing temporary crowns, bridges, inlays, onlays and splints. It has excellent flow to permit the restoration to be easily and completely seated. It is strong enough to withstand the stresses of mastication, yet permits easy removal of the restoration when this is desired. OraTemp NE is compatible with all conventional temporary crown and bridge materials, composite resin cements and composite resin core build-up materials.

Composition :

Base Paste : Zinc Oxide and Excipients.

Catalyst Paste : Octanoic Acid, Accelerator and Excipients.

Intended Purpose / Intended Use : It is intended to be used as temporary luting cement.

Indications for Use :

1. Temporary cementation of provisional restorations & final restorations.

2. The Product has been designed to remain in the mouth for upto 4 weeks.

Instructions for Use :

A. Preparation : Dry the prepared teeth and the surface of the restoration. Prior to cementation, a protective varnish (e.g., Shield Activ Desensitizer) may be applied to the clean and dry dentin surfaces. It should be brushed gently into the dentin for 10seconds using a suitable instrument (brush, applicator brush). Carefully disperse excess to a thin layer with blown air/dry with an air syringe. Do not over dry the dentin (carefully follow the instructions supplied with Shield Activ Desensitizer).

B. Application : Manual- Mix, Extrude equal lengths of Base and catalyst onto the mixing pad provided. The length to be extruded will depend on the size and type of restoration to be cemented. Replace cap tightly on cartridge after use. Thoroughly mix the pastes for approximately 30- 45 seconds. The dispensed material shall not be placed back in the container and the dose once applied or used shall not be reused.

C. Apply a thin layer of the mixed cement to the internal surfaces of the temporary restoration. Subsequently, seat the provisional restoration with light pressure. Excess cement can be removed after 3 minutes using a scaler or other appropriate instruments. Also, use a scaler and dental floss to remove any excess cement from the interproximal areas.

Notes :

1. To ensure an easy clean up and complete removal of excess, we recommended holding back the lip or cheek surfaces during the setting process, to prevent the excess material from spreading out into a thin layer.

2. During the self-curing process, the patient should not exert any pressure on the provisional restoration.

Working time : Approx. 1:30 -2:00 (minutes: seconds) at a room temperature of 25°C.

Self- curing time : Approx. 4 to 6 minutes at a room temperature of 25°C.

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 and hypersensitivity. If contact with skin occurs, immediately wipe off thoroughly with cotton soaked in 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.

Precautions :

1. Contact of unset material with the skin/ mucous membrane and the eyes should be avoided.

2. As individual components, the base and catalyst pastes have an irritating effect. Once mixed, however, they are not irritating.

Contraindications : Do not use in patients with known history of allergic to any of its ingredients or 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 and dry place.

Shelf Life : 3 years from date of manufacture.

Presentation :

Ref : 11003

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

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 :	01/02
Date :	30-03-2026

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

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, complaint and reporting of unexpected events contact customer care.