



ZOECem

Reinforced Zinc Oxide Eugenol Cement (Powder/Liquid)

ISO 3107

DIRECTIONS FOR USE

FEATURES:

The Zinc Oxide Eugenol filling material is reinforced with an acrylic resin to give good strength in order to withstand condens ation forces, as a lining material and mastication forces as a temporary restorative.

INTENDED PURPOSE: Base or liner under other restorative materials.

INTENDED PATIENT POPULATION: From child to geriatrics

This product has been formulated for use in dentistry and is intended for use by dental professionals only.

CLINICAL BENEFIT:To restore the function of the teeth and help maintain the integrity of the remaining tooth structure.

INDICATIONS FOR USE:

- Base or lining under restorative materials Temporary restorative.

CONTRA-INDICATIONS:

- Eugenol containing, the polymerisation of acrylic direct filling materials (acrylic resins and composite resins) as well as temporary crown or bridge materials is inhibited, use with these materials must be avoided.
- Do not use with patients who have a known hypersensitivity or severe allergic reaction to eugenol or any of the other components.
- Direct application to dental pulp (direct pulp capping)

CONTENTS OF PACK: Powder 40g, liquid 15ml, dropper pipette, instructions for use.

PRECAUTIONS AND WARNINGS:

- Liquid contains Eugenol
- Irritating to skin.
- Avoid contact with skin, oral mucosa and eves
- Do not expose patients or users known to be allergic to this type of material.

PROCEDURE (2) MIX RATIO:

The powder: liquid ratio is 4:1 (m:m)

(2) MIXING:

- Dispense powder and liquid onto a glass slab.
- Divide the powder into five parts.

 Using a steel spatula, mix in increments at 15-second intervals.

 Spatulate completed mix for 15 seconds.

Total mixing time: 1 minute 30 seconds

Working time: 2 minutes from end of mixing at 23°C.

Setting time: 6 minutes from placement in the oral cavity.

For test purposes, the ratio of powder 4.00g to liquid 1.00g tested at 23±1°C & RH 50±10%. ISO 9917-1 net setting time: 2 to 8 minutes from start of mix at 36-38°C & RH 90-100%.

(3) PLACEMENT:

- ADPLY mixed material to freshly cut cavity.

 If salivary contamination occurs, cleanse surface with Toothcleanser, wash and dry using oil-free air, prior to placement of materials.

STORAGE:



Store in a cool, dry place (5-25°C). Always replace cap immediately after use.

The expiry date is shown in year, month format. Do not use the product after this date

DISPOSAL:

Dispose of the contents and containers in accordance with relevant local and national requirements.

POSSIBLE SIDE EFFECTS / RESIDUAL RISKS:

This product contains substances that may cause and allergic reaction.

BATCH CODE:

The batch code gives an open date of manufacture in month, year, day format with a numerical suffix to uniquely identify the batch of material. Please quote this batch number in all correspondence.

DEVICE CODES:

AH0750 REF

40a Powder / 15ml Liquid

COMPOSITION

Composition	% by weight
Zinc Oxide	50 – 70
Reinforcing agents	1 – 5
Eugenol	30 – 50

MD

AHL operate a policy of continuing surveillance & monitoring of our products. If you experience any incidents relating to the use of this product, please immediately contact us at the above address stating the batch number shown on the packaging. If you experience any serious incident relating to the use of this product, please immediately contact AHL at the below address and the competent authority of the territory you are in.

A summary of safety & clinical performance (SSCP) is available via the EUDAMED database. https://ec.europa.eu/tools/eudamed
Caution: U.S. Federal Law restricts this device to sale by or on the order of a dental

professional



EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta 2025-03 AP9152/2





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