





Temporary Filling Material

DIRECTIONS FOR USE

A ready to use temporary filling material with a synthetic resin base. Adequate strength yet easily removed. Good sealing characteristic, easy to use consistency. It is not a permanent filling material and recommended use is up to a maximum of 4 weeks only.

INTENDED PURPOSE: Temporary restoration of lost tooth structure

INTENDED PATIENT POPULATION: From child to geriatrics

INTENDED USER:

This product has been formulated for use in dentistry and can be use by dental professionals or the general public.

CLINICAL BENEFIT:

To temporarily restore the function of the teeth and help maintain the integrity of the remaining tooth structure.

INDICATIONS FOR USE:

- Temporary filling of cavities Temporary sealing of inlay preparations Temporary sealing of endodontic treatments

CONTRA-INDICATIONS:

- Do not use for more than 4 weeks
 Any Purpose not Indicated above.

CONTENTS OF PACK: 30g Jar

- PRECAUTIONS AND WARNINGS:

 Do not expose users known to be allergic to this type of material.

 To avoid infection and/or serious injury, this product should not be used if there is throbbing pain, ulceration or swelling in the affected area.

 If any of these symptoms exist, consult your dentist immediately.

 This product should not be placed on open wounds.

 READ ALL OF THE DIRECTIONS CAREFULLY BEFORE USE!

 Wash and dry your hands.

 Do not get unused cement wet.

 Use only what is needed to repair the dental emergency.

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 DO NOT use product for any purpose other than indicated.
 You should consult a dentist within 24 hours of applying this product.
 Temporary filling material is only used as a temporary solution.
 Due to sensitivity to moisture, close the tube or jar immediately after removing the material, since otherwise the viscosity of the material increases (due to the entry of moisture), and the material may no longer be extractable.

PROCEDURE

(1) PLACEMENT:

- Using a suitable filling instrument, place direct into cavity and adapt as necessary. It is not essential to dry the cavity prior to placement.

 Temporary filling material hardens by absorption of moisture to give an impermeable
- seal. For provisional fixing of post crowns spread a layer on inside of crown and seat in normal
- way.

 Do not chew for the next 2 hours.
- For tube presentation, remove cap from tube, reverse and pierce membrane fully. Use key provided to assist extrusion from tube.

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.

 $\begin{array}{ll} \textbf{DISPOSAL:} \\ \textbf{Dispose of the contents and containers in accordance with relevant local and national} \end{array}$

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:

REF AH1000

30g Jar (White)

COMPOSITION

Composition	% by weight
Calcium Sulphate	50 – 60
Barium Sulphate	10 – 20
Glycol Ether	10 – 20
Zinc Oxide	5 – 15
Acrylic Polymer	0 – 5
Potassium Sulphate	0 – 5
Silica	0 – 5



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

Advanced Healthcare Ltd., Tonbridge, Kent, TN11 8JU, UK Tel: +44 1892 870500 Email:sales@ahl.uk.com

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013

Malta

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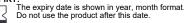
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