



AHL Generic



OTC TEMPORARY FILLING MATERIAL

DIRECTIONS FOR USE

FEATURES:

A ready to use temporary filling material with a synthetic resin base. Designed to replace a lost filling in case of emergencies. It has been developed to temporarily seal newly formed cavities and repair lost filling or inlays. It is not a permanent filling material and recommended use is up to 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

CONTRA-INDICATIONS:

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

CONTENTS OF PACK:

180X1 7g tube (Eugenol), instructions for use
293X1 7g tube (Cherry flavour), instructions for use

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.
- KEEP OUT OF REACH OF CHILDREN.
- 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) CAVITY PREPARATION:

- Wash and dry your hands thoroughly.
- Clean the cavity area.
- Carefully rinse out the cavity area with warm water.
- Remove excess water but leave moist do not dry cavity.

(2) PLACEMENT:

- Squeeze out a small amount of the filling material from the tube.
- Replace the lid to the tube.
- Roll the product between your fingers and make a small cone.
- Press the "cone" firmly into the cavity area.
- Scrape the material off your finger on the edge of your tooth do not lift directly off tooth as this could dislodge the filling material.
- Bite your teeth together gently several times this ensures that the filling material is in even line with the rest of your teeth.
- Wait 15 minutes for the filling material to start to set and remove any excess material.
- Do not chew for the next 2 hour to allow the material to fully set in contact with oral moisture.
- Avoid chewing directly on the filling material.

STORAGE:



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

EXPIRY:



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:



180X1 7g Tubes (Eugenol)
293X1 7g Tubes (Cherry flavour)

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
Eugenol	0 – 5
Cherry	0 – 1

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 below 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.



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FEEDBACK
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