



LIGHT CURED GLASS IONOMER RESTORATIVE COATING

ISO 6874:2015 Polymer based pit and fissure sealant

DIRECTIONS FOR USE

FEATURES:

A transparent light cure resin coating designed to protect and enhance glass ionomer restoratives.

INTENDED PURPOSE:

Protect the surface of restorations

INTENDED PATIENT POPULATION:

From child to geriatrics

INTENDED USER:

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

CLINICAL BENEFIT:

To help maintain the integrity of the remaining tooth structure.

INDICATIONS FOR USE:

Seal and protect the surface of glass ionomer restorations.

CONTRA-INDICATIONS:

- Do not use on patients with known allergies to resin based materials.
- Do not use with Eugenol containing restorative materials.
 If any sensitivity reactions are experienced, discontinue the use of the product and
- seek medical attention.

Do not use this product for any purposes other than specifically outlined under $\ensuremath{\mathsf{INDICATIONS}}$ in these instructions for use

CONTENTS OF PACK:

Liquid 5ml, instructions for use

PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- Irritating to oral mucosa, eyes and skin.
- May cause sensitisation by skin contact.
- In case of contact, rinse immediately with plenty of water and seek medical advice.
- Wear suitable gloves and eye/face protection.
- Avoid inhalation or ingestion of material.Do not mix with other products
- Do not mix with other products

PROCEDURE

(1) PLACEMENT:

- Place the glass ionomer according to manufacturer's instructions.
- When restoration has set, dry surface to be coated <u>do not desiccate</u>
- Dispense a few drops of the coating on to a suitable dish or mixing pad and replace the lid immediately.
- Apply coating with a disposable applicator within 2 minutes of dispensing and cure immediately, using a dental surgery light at 470nm for 20 seconds.
- Re-apply and cure following any subsequent adjustment or polishing

Note:

- Non-bur cut enamel should be treated with a 35-40% phosphoric acid according to the manufacturer's instructions. Rinse and dry with oil free air.
- Place light source as close as possible to the coated surface.
- If surface is tacky or yellowish, repeat light curing.

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:

5ml Bottle

•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	420X1
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COMPOSITION:

Composition	% by weight
Methacrylate resins	80 – 100
HEMA	20 - 30
Initiators	<1
Stabilisers	<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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