



LIGHT CURED GLASS IONOMER BASE LINER CEMENT (POWDER-LIQUID)

ISO 9917-2:2017 Resin-modified cements Class 3b

DIRECTIONS FOR USE

FEATURES:

HEMA free self-adhesive cement. Suitable for glass ionomer/composite "sandwich" restorations. Has good flexural strength. Mixes easily. Radiopaque. Contains fluoride.

INTENDED PURPOSE:

Base or liner under other restorative materials

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

INDICATIONS FOR USE:

- As a base or a liner. Deciduous cavity restoration.

CONTRA-INDICATIONS:

Pulp capping - use calcium hydroxide to line cavities where remaining dentin may be thin. Do not use eugenol-containing materials.

CONTENTS OF PACK:

Powder 15g, liquid 6ml, measuring scoop, instructions for use

PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- Avoid contact of liquid and powder with oral mucosa, eyes, and skin.
- In case of contact, wash thoroughly with water and obtain medical advice.
- DO NOT use product for any purpose other than indicated.
- Do not mix powder or liquid with other glass ionomer components.

PROCEDURE

(1) PREPARATION:

- Prepare cavity and clean with polyacrylic acid toothcleanser in normal way.
- Line deep cavities with calcium hydroxide if appropriate.

(2) MIXING:

Place <u>1 level scoop of powder</u> and 1 <u>bubble-free drops of liquid</u> on pad and mix thoroughly with flat bladed spatula to creamy consistency.

DO NOT ADD POWDER IN SMALL INCREMENTS.

Total mixing time: 30 seconds. Working time: 1 minute 30 seconds from start of mix at 23°C.

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

For test purposes, the ratio of powder 0.90g to liquid 0.20g tested at 23±1°C & RH 50±10%

ISO 9917-1 net setting time: 2 to 6 minutes from start of mix at 36-38°C & RH 90-100%.

(3) PLACEMENT:

Pack cement in to cavity and light cure the entire surface.

(4) CURING

- After placing and contouring the restoration, cure with a light unit.
- Select the light curing time in the table below.
- Light cure the entire surface of the restoration.
- For deep cavities, the layering technique is recommended, Place in a layer of up to 2mm depth and cure with a dental light cure unit.

Light Curing Unit	LED curing unit	Halogen lamp curing unit
Light Curing Time	10 seconds	20 seconds
Wavelength	440-490 nm	400-500 nm
Light Intensity	≥ 1000 mW/cm ²	≥ 500 mW/cm ²

- Use a dental light-curing unit having specifications equivalent to those described above.
- When using a unit having performance other than these recommendations, follow the instructions for that unit

(5) FINISHING:

After light curing or at 7 minutes after placement, the material is hard enough to allow placement of the primary restorative 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 LOT with a numerical suffix to uniquely identify the batch of material. Please quote this batch number in all correspondence.

DEVICE CODES:

346XA2BL 15g Powder / 6ml Liquid REF

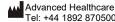
COMPOSITION:

Composition	% by weight
Glass	70 – 100
Deionised Water	5 – 10
PAA	5 – 10
Methacrylate resins	5 – 10
Stabiliser	<1
Activators	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 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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