



AHL Generic



LIGHT-CURE 1 STEP BOND (SELF-ETCHING)

DIRECTIONS FOR USE

FEATURES:

A HEMA-free "all-in-one adhesive" to etch, prime and bond in one step. It features ease of use and high bond strength to enamel and dentine, with good bond durability and biocompatibility. Suitable for use with composites and compomers.

INTENDED PURPOSE:

Bonding restorations to enamel and dentine

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:

- Bonding composites and compomers to enamel and dentine

CONTRA-INDICATIONS:

- Use on exposed pulp
- Use on pulpitis
- Patients with known allergy to methacrylate resin.

Do not use this product for any purposes other than specifically outlined under INDICATIONS in these instructions for use

CONTENTS OF PACK:

Liquid 6ml, mixing well, brushes, instructions for use

PRECAUTIONS AND WARNINGS:

- Close bottle or syringe after each use with the appropriate lid.
- In case of direct contact with the oral mucosa, rinse with plenty of water.
- Harmful if swallowed.
- Irritating to eyes and skin.
- May cause sensitisation by skin contact.
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- After contact with skin, wash immediately with plenty of soap and water.
- Wear suitable protective clothing, gloves and eye/face protection.
- Do not expose patients or users known to be allergic to this type of material. Isolated cases of contact-allergies with products of similar composition have been reported.
- To avoid possible pulpal reactions, protect the exposed dentine in the pulpal area with an appropriate lining material (preferably with a calcium hydroxide cavity liner).
- Avoid cavity liners which might inhibit polymerisation due to their components, e.g. phenolic substances such as zinc oxide eugenol.

PROCEDURE

(1) APPLICATION:

- Clean the tooth surface and prepare the cavity following conventional methods. Isolate with rubber dam if appropriate.
- Apply calcium hydroxide cavity liner in deep cavities where remaining dentine is thin.
- Apply a thin layer of adhesive and leave undisturbed for 10 seconds.
- Dry gently with oil-free air for 5 seconds.
- Light cure with dental curing light; Cure with a halogen light for 20 – 30 seconds. (The longer curing time is recommended to ensure total curing right down into the dentine tubules).
- Cavity is now ready for filling with composite or compomer restorative.

STORAGE:



Store in a cool, dry place (1-10°C).
Always replace cap immediately after use.
Do not expose to direct sun light or other heat sources.
Do not freeze.

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 an 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:



326X1 6ml Light-Cure 1 Step Bond (Self-Etching)

COMPOSITION:

Composition	% by weight
Initiators	1 – 5
Methacrylate Resins	20 – 30
Acetone	40 – 50
Water	20 – 30

* HEMA-free

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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