



# AHL Generic



## BONDING ADHESIVE (SINGLE PART) LIGHT CURING

### DIRECTIONS FOR USE

#### FEATURES:

A solvent-free, visible light curing Single Component Bonding Adhesive for enamel and dentine. It has an ability to moisten and penetrate the dentine. The product is a viscous non-thixotropic liquid. Only one application is needed, combines bonding agent and primer in a one-part formula. It is not compromised if the dentine is wet or dry, etched or unetched. Exhibits under various operational conditions an appropriate adhesion for composites and compomers to enamel and dentine as well as ensuring long lasting strong marginal adaptation.

#### 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
- Direct restorations
- Direct and indirect inlays, onlays and veneers.

#### 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:

Bottle 5ml, instructions for use

#### PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- 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.
- 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) CAVITY PREPARATION:

- Clean the tooth to be restored and adjacent teeth using a fluoride-free prophylactic paste.
- The cavity is prepared in the usual way.
- Bevelled margins improve adhesion and marginal adaptation.

##### (2) PULP PROTECTION:

- In areas close to the pulp use a thin layer of a suitable material such as calcium hydroxide liner.
- Do not use eugenol-containing cements.

##### (3) ETCHING

- Apply etch gel on enamel margins or enamel surfaces and etch as indicated in the directions for the etchant.
- In dentine-bounded cavities it is recommended to use the Total Etch Technique.
- Rinse thoroughly and dry with oil-free air.
- Keep dry.

##### (4) BONDING

- Dispense a sufficiently thick layer of Bonding Adhesive onto the etched enamel and dentine.
- With a brush or a cotton applicator tip, massage the Bonding Adhesive into the tooth for 20 seconds to achieve an even, glossy layer.
- 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).

**Caution:** Do not expose unused Bonding Adhesive to the operating or curing lights.

##### (5) FINISHING:

- Fill the cavity with composite resin restorative, following the directions supplied with the product.

#### STORAGE:



Store in a cool dry place.

Do not expose to direct sun light or other heat sources.

If room temperature is likely to exceed 25°C storage in a refrigerator is recommended.

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:



250X1

5ml Bonding Adhesive Bottle

#### COMPOSITION:

Composition	% by weight
Polyacrylic acid	0 – 5
Methacrylate Resins	60 – 80
2-HEMA	15 – 25
Initiators	1 – 5
Stabilisers	<1
Water	0 – 10

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.



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



Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatara, BKR 4013 Malta.

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**FEEDBACK**

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