



AHL Generic  0123

ETCH GEL

DIRECTIONS FOR USE

FEATURES:

Optimum viscosity for easy extrusion with thixotropic 'non-drip' effect to remain where applied. Syringe presentation for ease of application. Bright colour to ensure precise placement is achieved. Treatment of enamel margins of class I, II, III and V composite restorations to prevent microleakage.

INTENDED PURPOSE:

Preparation of enamel to help retain resin based dental 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:

- Condition of enamel (and dentin where the total etch technique is desired) prior to adhesive materials placement

CONTRA-INDICATIONS:

- Use on dental pulp tissue
- Do not use this product for any purposes other than specifically outlined under INDICATIONS in these instructions for use

CONTENTS OF PACK:

071X1 5ml Syringe, 10 tips, instructions for use
 024X3 5ml Syringe, 10 tips, instructions for use
 024X6 12ml Syringe, 20 tips, instructions for use
 071X3 50ml Bottle, instructions for use
 024X2 50ml Bottle, instructions for use
 071X6 50ml Syringe, 60 tips, instructions for use
 024X4 50ml Syringe, 60 tips, instructions for use

PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- The Etch-Gel contains 40% phosphoric acid.
- Corrosive.
- Causes burns.
- Avoid contact with eyes, skin, and oral mucosa.
- In case of accidental contact, rinse immediately with plenty of water and seek medical advice.
- In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

PROCEDURE

(1) FILLING APPLICATOR SYRINGE: (applies to economy 50ml syringe only)

- Remove caps from both syringes; making sure the connector remains on the large syringe.
- Attach the small applicator syringe to the connector on the large syringe with the piston of the small applicator syringe depressed to the end of the barrel.
- Ensure that the small applicator syringe is securely attached to the large syringe by twisting the small applicator syringe clockwise until tight.
- Apply pressure on the piston of the large syringe to deliver a flow of material from the large syringe to the small applicator syringe.
- If the flow of material shows resistance; pull the piston of the small applicator syringe simultaneously.
- To detach, retract piston of large syringe slightly to avoid leakage, then remove the small applicator syringe and clean any excess material with a paper towel.
- Replace appropriate caps to both syringes when not in use.

(2) APPLICATION:

- If the enamel surface has not been freshly exposed by cavity preparation or tooth reduction, cleaning with oil-free prophylaxis paste or pumice and water is recommended.
- Syringe the etch-gel directly on to the enamel surfaces to be treated.
- The gel can be spread using the Syringe tip or any other suitable instrument (small ball-ended plunger or brush.)
- Leave etch gel in place for 30 seconds.
- Wash and dry using oil-free air.
- Enamel surface should have a dull frosted appearance.
- If not, repeat procedure as above. Secure tip cap immediately after use.
- Do not force plunger; if blocked, replace tip.

SINGLE USE

 Do not reuse tips due to hygienic reasons (prevention of cross-contamination between patients).

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 an allergic reaction.
- Corrosive.
- Causes burns.

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	Device Code	Description
071X1	071X1	5ml Syringe Blue Gel, 10 tips
024X3	024X3	5ml Syringe Green Gel, 10 tips
024X6	024X6	12ml Syringe Green Gel, 20 tips
071X3	071X3	50ml Bottle Blue Gel
024X2	024X2	50ml Bottle Green Gel
071X6	071X6	50ml Syringe Blue Gel, 60 tips
024X4	024X4	50ml Syringe Green Gel, 60 tips

COMPOSITION:

Composition	% by weight
Phosphoric Acid	35 – 45
Deionised Water	50 – 60
Silica	1 – 10
Solvent	0 – 5
Pigment	0 – 5
Xanthan Gum	<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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