

Phosphoric Acid Etching Gel

(Instructions for Use)

Version: 01

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U.S. Federal Law restricts this device to sale by or on the order of a dental professional. Prior to use the product, please read the instruction carefully.

GENERAL DESCRIPTION

Phosphoric Acid Etching Gel is a flowable gel with excellent water solubility and miscibility. Using a disposable dispensing tip, Phosphoric Acid Etching Gel can be directly applied onto the tooth surface. Its color is blue, which can be identified easily on tooth or a repairing surface with contrast.

Model(s): E20, E25, E30, E32, E35, E37, E38

Phosphoric Acid Etching Gel is used as an auxiliary material in the dental bonding procedure followed by the use of Light Cure Dental Adhesive.

INDICATIONS

Used for etching of tooth enamel and/or dentin prior to the applications of bonding direct filling, repairing or enamel surface coating materials, as well as cementation of indirect restorations such as crowns, bridges, inlays/onlays, veneers, posts, splints, orthodontic brackets, etc. made of resin composites, porcelains/ceramics, metals and their combinations. Can also be used for cleaning of restoration surfaces prior to repairing or cementation.

CONTRAINDICATIONS

Not for exposed pulp or pulpitis needing treatment.

SIDE EFFECTS

This product or one of its components may cause hypersensitive reactions.

MAIN COMPONENTS

Water, phosphoric acid, thickening and coloring agents.

OPERATING PROCEDURES

1. Preparation prior to etching

1.1 Clean the bonding site per common operation procedures.

1.2 Isolate the teeth being treated with rubber dam.

1.3 Take a dispensing tip and lock it onto the syringe, making sure the tip is tightened and the etching gel can be dispensed first under pressure extraorally.

2. Tooth etching

2.1 Total etch: Dispensing enough Phosphoric Acid Etching Gel and spread to the whole bonding site, usually to the enamel area first, then to the dentin area. In general, for enamel, the etch time is about 15 - 30 seconds, while for dentin is about 10 - 20 seconds. When washing off the etching gel, rinse the etching site using a stream of water (0.2 -0.4 MPa pressure) for at least 10 seconds while using suction tube to dry the field simultaneously. Dry lightly the tooth surface afterwards.

2.2 Selective etch: Only etch the area of choice, such as the enamel area. Follow the etching time and washing procedure indicated above accordingly.

· Note: Please dry with clean, oil-free, air without desiccating the dentin to avoid post-operative sensitivity. Do not allow etched surface to become contaminated with saliva or blood during the bonding procedure.

NOTE

· Never use excessive force on syringe plunger to dispense etch which may lead to over dispensing of the material. If resistance is felt replace current tip with a new tip and check flow extra-orally.

· Refer to outer package for expiration date. Do not use after expiration date.

· Notification of any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

PRECAUTIONS

- Contains phosphoric acid. Avoid contact with skin, eyes and soft tissue. In case of contact with skin or eyes, flush immediately with water. Get medical attention for eyes. Do not take internally.
- Dispensing Tips or etching gel tips are for single use only, to prevent cross-contaminations between patients.
- Disposal must be made in accordance with local regulations.
- If one of the following is noted, it is a sign that the material is losing its efficacy and should no longer be used:
 - the etching gel has thickened noticeably and having difficulty to be extruded from the syringe.
 - the color of the etching gel is faded or become colourless.
 - the etching gel has a tendency to back flow instead of dispensing through the dispensing tip.

STORAGE

- Store Phosphoric Acid Etching Gel at 2-25°C, away from direct light. Use the material at normal room temperature.
- Shelf life: 2 years from date of manufacture

PACKAGES

1. Phosphoric Acid Etching Gel

2. Dispensing tips

Packaging specifications: 1ml, 2.5ml, 3ml, 5ml, 10ml, 30ml, 1g, 2.5g, 3g, 5g, 10g, 30g.

WARRANTY

Rizhao HuGe Biomaterials Company, Ltd. warrants this product is free from defects in material and manufacture. HUGE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and HUGE's sole obligation shall be repair or replacement of the HUGE product.

LIMITATION OF LIABILITY

EXCEPT WHERE PROHIBITED BY LAW, HUGE WILL NOT BE LIABLE FOR ANY LOSS OR DAMAGE ARISING FROM THIS PRODUCT, WHETHER DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL, REGARDLESS OF THE THEORY ASSERTED, INCLUDING WARRANTY, CONTRACT, NEGLIGENCE OR STRICT LIABILITY.

SYMBOLS FOR USE IN THE LABELING

-  - Use-by date
-  - Caution
-  - Batch code
-  - Temperature limit
-  - Country of manufacture
-  - Consult instructions for use
-  - Keep dry
-  - Keep away from sunlight
-  - Unique device identifier
-  - Authorized representative in the European Community
-  - Medical device
-  - Manufacturer
-  - Warning; Corrosive substance

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