ETCHANT - ETCHO-37

(Orthophosphoric Acid Etching Gel)

INSTRUCTIONS FOR USE (Please read carefully before use)

Doc. No: **HH/IFU/10** Approved By: **Mr. Vikram Vora** Language: **English**

Revision	01/01
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PRODUCT DESCRIPTION: Etchant is a gel for etching enamel and dentine. Within 15–30 seconds of application, enamel becomes chalky in colour — the surface roughens, increasing adhesion of restoration materials to enamel. On dentine, orthophosphoric acid forms acid phosphates with dentine calcium and the smear layer; the gel removes the smear layer, opens dentinal tubules and alters the dentine surface, providing high adhesion of restorative materials to dentine and enamel. The gel is water-based and removes easily with water and air. For use in an aggressive biological medium between 32–42°C (oral cavity 37±1°C, humidity 60–90%).

MATERIAL OF CONSTRUCTION: Orthophosphoric acid (37%), gel-forming agent with aqueous base.

INDICATIONS: Enamel and dentine etching according to the acid-etching technique.

CONTACT TIME: Enamel 30 sec; dentine 15 sec; combined dentine and enamel treatment 30–45 sec.

PROCEDURE & PRODUCT HANDLING:

- Apply a small amount of gel to the prepared, dried enamel surface (contact time 30 sec) or dentine surface (contact time 15 sec). For combined dentine and enamel treatment, contact time is 30–45 sec.
- Wash the gel off with water and dry with compressed air.

CAUTION / WARNING:

1. Device to be used by a qualified dentist or dental technician only.
2. Use with great care in allergic patients. Do not misuse.

CONTRAINDICATIONS:

1. Do not use the product if the patient is allergic to any of the ingredients.
2. Drug idiosyncrasy.

INTERACTIONS WITH OTHER DENTAL MATERIALS: Kindly communicate and inform the manufacturer with complete details in case of any incidences of interaction not mentioned here.

ADVERSE REACTIONS: No known side effects when all terms of application, transport and storage are observed. Kindly communicate and inform the manufacturer in details of any instance.

PACKAGING: Etchant, 3 ml or 10 ml syringe.

STORAGE CONDITIONS: Keep away from direct sunlight. Keep locked up and out of the reach of children. Store at a temperature between 5°C to 25°C in a well-sealed container. Close tightly after use.

SHELF LIFE: 2 years from the date of manufacturing.

DISPOSAL: Dispose in accordance with local, state and federal environmental regulations.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel.

Symbol for “BATCH CODE”	Symbol for “USE BY”	Symbol for “NON STERILE”
Symbol for “KEEP DRY”	Symbol for “CAUTION”	Symbol for “CONSULT INSTRUCTIONS FOR USE”
Symbol for “CATALOGUE NUMBER”	Symbol for “KEEP OUT OF THE REACH OF CHILDREN”	Symbol for “MANUFACTURER”
Symbol for “DO NOT USE IF PACKAGE IS DAMAGED”	Symbol for “TEMPERATURE LIMITATION”	Symbol for “KEEP AWAY FROM SUNLIGHT”
Symbol for “MEDICAL DEVICE”	Symbol for “COUNTRY OF MANUFACTURE”	

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Kindly retain the instructions for use & packaging box until the complete use of the product / expiry.

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.