

# Etchant Gel S

## Instructions for use

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Please read the instructions for use carefully before using the product.

## PRODUCT DESCRIPTION

Etchant Gel S is a phosphoric acid etching gel.

## INTENDED USE

Etchant Gel S is used for etching enamel and dentin during adhesive dental protocols.

## COMPOSITION

Component*	wt %
Water	40-55
Phosphoric acid	35-45
Amorphous silica	1-10
Polyethylen glykol-Monomethylether	5-15

\* Components present in very low concentrations (<1.0%) are not listed

## INDICATIONS

Permanent restoration of hard structures in the mouth.

## CONTRAINDICATIONS

Contraindicated in the case of hypersensitivity to any of the ingredients.

## SAFETY INSTRUCTIONS

### Safety

- Causes acid burns.
- Keep out of the reach of children!
- For hygienic reasons, the application needles are intended for single use only.
- Always wear gloves and safety goggles (for both doctor and patient).
- Avoid bringing Etchant Gel S into contact with gingiva, pulp or adjacent teeth.
- In case of direct contact with the oral mucosa, rinsing with tap water is sufficient. In the case of contact with the eyes, rinse thoroughly with water and consult an ophthalmologist showing these instructions for use.
- Contains nano materials (bonded particles).

### Residual Risks

Users should be aware that any dental intervention in the oral cavity involves certain risks. Some of these risks are:

- Loss of marginal integrity / restoration.
- Postoperative sensitivity / irritation of gingiva / secondary caries / endodontic complications
- Discoloration / wear

## SIDE EFFECTS / INTERACTIONS

No systemic side effects are known. If brought into contact with the etched and dried enamel, saliva will destroy the adhesive system's bonding effect.

## USER- / PATIENT GROUP

The product shall be used by qualified dental professionals only. Suitable for all patient groups.

Note: This product has not been specifically tested in vulnerable patient groups such as children or pregnant or lactating women.

## PREPARATION

### Cleansing the tooth

Cleanse tooth to be treated and the adjacent teeth using a brush and prophylaxis paste which does not contain fluoride.

### Keeping work dry (dental dam)

Use a dental dam (e.g. from COLTENE) for safety reasons and for draining.

## Preparing the cavity

According to the principle of the adhesive restoration technique. If indicated, a punctiform cap should be placed near the pulp using a material suitable for use as pulp caps. Finish the enamel with a diamond grinder in case of contamination.

## PROPER USE

Apply Etchant Gel S directly from the applicator needle onto the surface to be treated. Allow the etchant to remain in place for 15 s on enamel and dentine. Afterwards, rinse thoroughly with water (approx. 20 s), until all traces of Etchant Gel S have been removed. Gently dry with oil-free compressed air, taking care not to overdry dentine. Proceed with the adhesive according to manufacturer's instructions for use. Etched enamel has a chalky white appearance. In case of doubt, repeat etching procedure.

Note: Use fluoride on enamel which has been etched and is not covered by composite.

## REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

For the syringe, the use of a disposable sleeve is recommended. In case of suspected or identifiable contamination, dispose of the syringe as described below.

Disinfection in a washer-disinfector or steam sterilization in an autoclave is not possible.

## SHELF LIFE / STORAGE

Expiry date and **LOT**: See primary packaging

Storage temperature: 4-23°C / 39-73°F

Shelf life after first opening: 3 months

Protect against exposure to heat and sun. Avoid extreme temperature fluctuations.

## DISPOSAL

Dispose of product waste according to applicable legislation. Special country-specific regulations may apply. Dispose only of completely emptied packages together with household waste in compliance with official regulations.

## REPORTING OBLIGATION

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.

In the unlikely event of inhalation, ingestion, eye contact, or similar incidents seek immediate medical attention from an appropriate medical specialist to mitigate potential harm.

## SAFETY DATA SHEET (SDS)

[www.coltene.com](http://www.coltene.com)



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## Glossary



Consult instructions for use



RX only



Medical Device



Legal Manufacturer



European Authorized Representative



Importer



Reference Number



Manufacturing Date



Expiry Date



Batch Code



Unique Device Identifier



Single use only



Keep away from sun light



Temperature limitation

## COLTENE International Dental Group

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CH-9435 Heerbrugg

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Coltene/Whaledent AG  
Feldwiesenstrasse 20  
CH-9450 Altstätten

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