Product Description:
A blue, water-based etching gel containing 40% phosphoric acid. The blue tint provides visual contrast against the enamel.

Intended Use:
For use by a licensed dentist for etching tooth enamel to promote adhesion of restorative materials such as dental composites and bonding agents.

Indications for Use:
- Enamel conditioning for adhesive materials
- Preparation for composite resin, sealants, or bonding systems

Contraindications:
- Do not use on patients with known hypersensitivity to phosphoric acid or any component of the gel
- Not recommended for patients with active oral ulcerations or open gingival lesions

Warnings:
- **Rx only**. For professional use only
- Corrosive: May cause burns to skin, eyes, and mucosa
- Do not ingest or inhale
- Avoid contact with soft tissue
- Use only in well ventilated areas
- Keep out of reach of children
- Use personal protective equipment (PPE): gloves, goggles, mask

INSTRUCTIONS FOR USE

ZenithDental™
Enhancing dentistry with education and technology®

Product Name:
ZenithDental™ 40% Phosphoric Acid Dental Etching Gel
Catalog Number: 003-61901
UDI: +D033003619011
Manufacturer:
DMG America LLC
242 South Dean Street
Englewood, NJ 07631 USA, Made in USA
(201) 894-5505 • (800) 662-6383
www.dmg-america.com
Emergency Response Phone Number:
Infotrac—1-800-535-5053





IFU Version: Rev. 06/25, Part# 04-019

Precautions:
- Avoid over-etching which can lead to dentin hypersensitivity or poor adhesion
- Dispensary Needles are **single use only**. Use a new dispensary needle for each patient to prevent cross-contamination, clogged tip and sudden expulsion of gel
- Dispose of dispensary needles and all used contaminated materials per clinical waste guidelines

Instructions for Use:
1. **Preparation:** Clean and isolate the tooth. Dry using air free of oil and water.
2. **Application:** Remove cap from syringe, set aside for proper storage of syringe after application of gel is complete. Attach a new dispensary needle to the syringe. Apply gel to enamel only. Avoid dentin.
3. **Etching time:**
- **Permanent teeth:** 15 seconds
- **Primary teeth/High fluoride:** 90-120 seconds
4. **Rinse:** Rinse thoroughly with water for at least 20 seconds.
5. **Inspection:** A frost white enamel surface should appear. Reapply only if required.
6. **Accidental soft tissue exposure:** Rinse area immediately with copious water. Monitor for irritation.

Instructions for Use: *(Continued)*

7. If accidental contact with dentin occurs, rinse thoroughly and evaluate before continuing.

8. Remove and properly dispose of dispensary needle and recap syringe tightly to prevent leakage.

Potential Adverse Effects:

- Skin, mucosa or eye irritation
- Dentin Hypersensitivity
- Allergic contact dermatitis
- Gastrointestinal distress if ingested
- Anxiety or pain from accidental soft tissue contact
- **Carcinogenicity:** None known

First Aid: (Patient, Clinician and Dental Staff)

Inhalation: Move to fresh air, administer oxygen if needed, seek medical attention.

Skin Contact: Remove contaminated clothing. Rinse skin under running water for 15-20 minutes. Seek medical attention.

Eye Contact: Flush eyes with water for at least 15-20 minutes, lifting eyelids occasionally. Seek immediate medical care.

Ingestion: Do not induce vomiting. Rinse mouth. Dilute with water or milk. Get emergency medical help.

Storage and Handling:

- Storage range: 4°C (40°F) to 25°C (77°F)
- Keep away from sunlight and heat sources

Storage and Handling: *(Continued)*

- Keep container tightly closed when not in use
- Negligible fire hazard when exposed to heat or flame

Disposal:

- Dispose of chemical waste in accordance with local hazardous waste regulations
- Contaminated items must be treated as clinical waste

Composition:

Active Ingredient: 40% Phosphoric Acid

Appearance: Blue Odorless gel

ph: 1.5 (0.1N Solution)

Specific Gravity: 1.3

Solubility: Fully water soluble

Labeling Symbols:

