



Enamel Pro®

Professional Prophylaxis Paste



premier Inspired solutions for daily dentistry®



Manufacturer:
Premier® Dental Products Company
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premierdentalco.com/promise

Intended Use:

It is to be used as a preventative treatment. It is intended to polish and clean teeth with varying grit particulates of silica as an abrasive agent while formulated to deliver amorphous calcium phosphate (ACP) in order to increase fluoride uptake during the procedure to stimulate remineralization of teeth. In packages indicating that Enamel Pro Contains fluoride, it is present at a concentration of 1.23% fluoride ion.

Indications for Use:

Indicated for normative preventative dental treatments for stain removal and polishing

Available in the following grits:

Fine	For gentle polishing, ideal for younger patients.
Medium	For normal adult cleaning procedures where high level of polish and plaque removal is desired.
Coarse	For adult patients with substantial stain build-up.
Extra Coarse	For those select patients who have stain build-up difficult to remove.

Product Description:

Product line contains professional prophylaxis paste for tooth cleaning and polishing formulated to deliver amorphous calcium phosphate in order to increase fluoride uptake provided in a variety of flavors. Non-fluoride formulations are optional.

Contraindications:**Do not use under the following conditions –**

- Product contains fluoride, if patient displays or has a history of fluoride sensitivity.

PRECAUTIONS:

- Keep product stored within its original packaging and within the storage conditions as indicated on the labeling.
- Single patient use only. Do not reuse.
- Rx only, Prescription device.

WARNINGS:

- Harmful if swallowed: Fluoride ingestion can cause nausea.
- Causes serious eye irritation.
- Causes skin irritation.

Adverse Reactions:

- Nausea and vomiting may occur from the ingestion of pastes.

If a serious incident has occurred in relation to the device, please report the incident to the Manufacturer and/or competent authority of the Member State where the device was used.

Contents and Setup:

Refer to premierdentalco.com for a full list of flavors and offerings.

Materials:

In packages indicating that Enamel Pro contains fluoride, it is present at a concentration of 1.23% fluoride ion. Available in non-fluoride formulation.

Enamel Pro contains pumice, abrasiveness of pumice varies with grit.

Directions for Use:

1. Unit dose cups – Each cup contains enough Enamel Pro Paste for one (1) prophylaxis procedure.
2. Using any commercially available Prophy angle – rubber cup combination.
3. Fill the cup by pressing the face of the cup into the paste while running the angle at low speed. The “swirl” design for aesthetic purposes only. All contents in the cup will provide the same benefits to your patient’s teeth.
4. Throughout the procedure, sufficient paste should be maintained on the cup to avoid overheating of the tooth surface.
5. Saliva evacuation is recommended to avoid excess dilution and swallowing of the paste.
6. Should you find the paste too dry for your preference, simply add a drop or two drop of water to soften.

Storage:









Store in temperature conditions of 15° (59°) to 30° (86°) and away from direct sunlight.

Shelf Life:

Shelf life of the product is two (2) years from the date of manufacturing and labeled on the product.

For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbols	Symbol Meaning
	Temperature Limit
	Warning, See IFU
	SKU
	Do not reuse
	Irritant
	Manufacturer
	Medical Device
Rx ONLY	Professional Use Only
	UKCA