

Ziroxide™

Professional Prophylaxis Paste







Manufacturer:
Premier® Dental Products Company
1710 Romano Drive,
Plymouth Meeting, PA 19462 U.S.A.
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Intended Use:

It is to be used as a preventative treatment. It is intended to be used as a deep stain removal and polishing agent which contains large grit particles of zirconium silicate. In packages indicating that Ziroxide contains fluoride, it is present at a concentration of 1.23% fluoride ion.

Indications for Use:

Indicated as a preventative dental treatment to remove tougher stains with larger grit sizes and polish teeth.

Available in the following grits:

Medium/Fine	For normal adult cleaning procedures where high level of polish and plague removal is desired.	
Coarse	For adult patients with substantial stain build-up difficult to remove.	

Product Description:

Product line containing professional prophylaxis paste for polishing and deep stain removal containing zirconium silicate and fluoride 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:

Available in a natural mint flavor

Materials:

In packages indicating that Ziroxide contains fluoride, it is present at a concentration of 1.23% fluoride ion. Non-fluoride formulations will contain zirconium silicate.

All Ziroxide will contain different grade pumice as abrasive material. Abrasiveness of pumice varies with grit.

Directions for Use:

- 1. Unit dose cups Each cup contains enough Ziroxide Paste for one (1) prophylaxis procedure.
- 2. Bulk Jar Remove sufficient paste for one procedure and place in a clean dappen dish or other suitable container.
- 3. Using any commercially available Prophy angle rubber cup combination.
- 4. Fill the cup by pressing the face of the cup into the paste while running the angle at low speed. All contents in the cup will provide the same benefits to you patient's teeth.
- 5. Throughout the procedure, sufficient paste should be maintained on the cup to avoid overheating of the tooth surface.
- 6. Saliva evacuation is recommended to avoid excess dilution and swallowing of the paste.
- 7. 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
30°C 15°C / 86°F 59°F	Temperature Limit
\triangle	Warning, See IFU
REF	SKU
(2)	Do not reuse
<u>(1)</u>	Irritant
•••	Manufacturer
MD	Medical Device
R _X ONLY	Professional Use Only
UK CA	UKCA