ENAMELON PREVENTIVE TREATMENT- stannous fluoride gel
Premier Dental Products Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Enamelon Gel

Active ingredient

Stannous fluoride 0.40% (0.15% w/v fluoride ion)

Purpose

Anticavity/Sensitivity Relief/Antigingivitis

Uses

- Aids in the prevention of cavities
- Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact
- Helps prevent gingivitis
- Helps interfere with the harmful effects of plaque associated with gingivitis

Warnings

Keep out of the reach of children.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. **Do not use if** gingivitis, bleeding, or redness persists for more than 2 weeks, see your dentist. See your dentist immediately if you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. **Stop use and ask a dentist if** the problem persists or worsens. Do not use this product for sensitivity relief longer than 4 weeks unless recommended by a dentist or doctor.

Directions

Adults and children 6 years of age or older: Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not rinse, eat or drink for 30 minutes after brushing. Instruct children under 12 years of age in the use of this product (to minimize swallowing). Supervise children as necessary

until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.

Other information

This is an anticavity/fluoride preventive treatment gel, not a toothpaste. Read directions carefully before using. Products containing stannous fluoride may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

- Do not use if foil seal is broken or missing
- Keep tightly closed when not in use
- Store at controlled room temperature

Inactive ingredients

Acesulfame K, calcium/sodium maleate methyl vinyl ether copolymer, calcium sulfate, cocamidopropyl betaine, dimethicone, flavors, glycerin, lauroyl-sarcosine, monosodium phosphate, poloxamer 407, polyethylene glycol, silica, sucralose

Questions or comments?

Call toll-free 1-888-670-6100
Monday-Thursday 8am-5pm EST, Friday 8am-4pm EST

United States Patent Numbers: US 5,993,784, US 5,711,936, US 5,651,959 and other patents pending. Made in U.S.A.

Ultramulsion® is a registered trademark of WhiteHill Oral Technologies, Inc.

Clinically Proven Active Ingredient for Anticavity, Antigingivitis and Sensitive Teeth

- Relieves the discomfort of dry mouth tissues
- Non-irritating to patients with dry mouth
- Optimized with calcium and phosphate ions
- No Sodium Lauryl Sulfate (SLS), No Gluten, No Dyes

Distributed by:

Premier ® Dental Products Company, Plymouth Meeting, PA 19462

www.premusa.com Part # 9007285 www.enamelon.com

NDC 48783-500-40 021665 Rev4 SP

PRINCIPAL DISPLAY PANEL

STRENGTHEN YOUR SMILE!

ACP ™ Enamel Therapy

Premier ®

Enamelon ®

Preventive Treatment Gel

NET WT 4.0 OZ (113 g)

SENSITIVITY & DRY MOUTH

Clean Mint

HYDRAMULSION ®

ENAMELON PREVENTIVE TREATMENT

stannous fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:48783-500
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.004 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
CALCIUM/SODIUM MALEATE METHYL VINYL ETHER COPOLYMER (1000000 MW, 1900 MPA.S AT 11%) (UNII: 5216H1HX5F)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAUROYL SARCOSINE (UNII: LIJ19P3L6F)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor	MINT (Clean Mint)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48783-500-40	1 in 1 CARTON	01/01/2014	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/01/2014	

Labeler - Premier Dental Products Company (014789663)

Revised: 1/2023

Premier Dental Products Company