

# **ENAMELON PREVENTIVE TREATMENT- stannous fluoride gel**

## **Premier Dental Products Company**

-----

### **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](http://www.premusa.com) Part # 9007285 [www.enamelon.com](http://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®

STRENGTHEN YOUR SMILE!®

**premier.** Enamelon® Preventive Treatment Gel

Clean Mint NET WT 4.0 OZ (113 g)

HYDRAMULSION®

ACP®  
Enamel Therapy

STRENGTHEN YOUR SMILE!®

**premier.** Enamelon® Preventive Treatment Gel

Clean Mint NET WT 4.0 OZ (113 g)

HYDRAMULSION®

ACP®  
Enamel Therapy

+D69190072850F

THE PREMIER Promise EVERY TIME  
premierdentalco.com/promise

<b>Drug Facts</b> <b>Active ingredient</b> Stannous Fluoride 0.40% (0.12% w/w fluoride ion) <b>Purpose</b> Anticavity/Sensitivity/ Antigingivitis <b>Uses</b> <ul style="list-style-type: none"><li>Aids in the prevention of cavities</li><li>Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact</li><li>Helps prevent gingivitis</li><li>Helps interfere with the harmful effects of plaque associated with gingivitis</li></ul>	<b>Drug Facts (continued)</b> <b>Warnings</b> 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 see 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.	<b>Drug Facts (continued)</b> <b>Directions</b> 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.
<b>Drug Facts (continued)</b> <b>Other information</b> This is an antihydroxyapatite 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. <ul style="list-style-type: none"><li>Do not use if foil seal on tube is broken or missing</li><li>Keep tightly closed when not in use</li><li>Store at controlled room temperature</li></ul>	<b>Drug Facts (continued)</b> <b>Inactive ingredients</b> Calcium sodium pyrophosphate, calcium sulfate, cocamidopropyl betaine, dimethicone, fluoroaluminum glycerol, lauryl sarcosinate, monosodium phosphate, polyoxamer 407, PEG-12, potassium acesulfame, silica, sucralose <b>Questions or comments?</b> Call toll free 1-888-670-8100 <b>United States Patent Numbers:</b> 8,159,925 (to US), 8,961,094 (to US), 8,940,076 (to US), 7,941,542 (to US), 8,104,044 and other patents pending. <b>Distributed by:</b> Premier® Dental Products Company, Plymouth Meeting, PA 19462 Made in the U.S.A. - premierdentalco.com - enamelon.com	<b>Clinically Proven Active Ingredient for Anticavity, Antigingivitis and Sensitive Teeth</b> <ul style="list-style-type: none"><li>Relieves the discomfort of dry mouth tissues</li><li>Non-irritating to patients with dry mouth</li><li>Helps protect against painful sensitivity</li><li>Optimized with calcium and phosphate ions</li><li>No sodium lauryl sulfate (SLS), no gluten, no dyes</li></ul> <p>THE PREMIER Promise EVERY TIME</p> <p>Daily Dentistry® NDC 48783-500-40 Part # 9007280 - 12/2002 Rev 7 SP</p>

ENAMELON PREVENTIVE TREATMENT

stannous fluoride gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:48783-500
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ACESULFAME POTASSIUM</b> (UNII: 230V73Q5G9)	
<b>CALCIUM SULFATE</b> (UNII: WAT0DDB505)	
<b>CALCIUM/SODIUM MALEATE METHYL VINYL ETHER COPOLYMER (1000000 MW, 1900 MPAS AT 11%)</b> (UNII: 5216H1HX5F)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LAUROYL SARCOSINE</b> (UNII: LIJ19P3L6F)	
<b>SODIUM PHOSPHATE, MONOBASIC</b> (UNII: 3980JIH2SW)	
<b>POLOXAMER 407</b> (UNII: TUF2IWW3M2)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Clean Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
---------------------------	---	-----------------------------	---------------------------

OTC Monograph Drug	M021	01/01/2014	
--------------------	------	------------	--

**Labeler** - Premier Dental Products Company (014789663)

Revised: 1/2026

Premier Dental Products Company