

## **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.*

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#### **Active ingredient**

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

#### **Purpose**

Anticavity/Sensitivity Relief/Antigingivitis

#### **Uses**

- Aids in the prevention of caries
- 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 sulfate, cocamidopropyl betaine, dimethicone, flavors, glycerin, lauroyl-sarcosine, monosodium phosphate, poloxamer 407, polyethylene glycol, pva/ma copolymer, silica, sucralose

### **Questions or comments?**

Call toll-free 1-888-670-6100 Monday-Friday 8am – 5pm EST

### **Distributed By**

Premier® Dental Products Company, Plymouth Meeting, PA 19462

[www.premusa.com](http://www.premusa.com) [www.enamelon.com](http://www.enamelon.com)

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.

### **PRINCIPAL DISPLAY PANEL**

STRENGTHEN YOUR SMILE!

ACP™ Enamel Therapy

Premier®

Enamelon Preventive Treatment Gel

Clean Mint

NET WT 4.0 OZ (113 g)

ULTRAMULSION®

**Questions or comments?**  
 Call toll-free 1-888-670-6100  
 Monday-Friday 8am-5pm EST  
 Retain original packaging for future reference.



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 Premier Dental Products Company, Plymouth Meeting, PA 19462  
 www.premia.com Part # 9007285 www.enamelon.com  
 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 Whitehall Oral Technologies, Inc.  
 NDC 48783-500-40 051438 Rev2 SP

**Enamelon®**

**Clinically Proven Active Ingredient for  
 Anticavity, Antigingivitis and Sensitive Teeth**

- Ultramulsion® is a patented saliva-soluble coating that moisturizes and soothes soft tissues of the mouth
- Clean Mint flavor enhanced with spearmint, a natural herb which can boost saliva flow and flavor
- No Sodium Lauryl Sulfate (SLS), No Gluten, No Dyes

STRENGTHEN YOUR SMILE!



**Enamelon®**  
 Preventive Treatment Gel  
 Clean Mint NET WT 4.0 OZ (113 g)

ULTRAMULSION®

Sample Inside! Enamelon® Fluoride Toothpaste NET WT 0.75 OZ (21.2 g)

**Enamelon® Preventive Treatment Gel**

| Drug Facts  | Drug Facts (continued)   | Drug Facts (continued)  |
|---|--|---|
| <p><b>Active Ingredient</b><br/>           Stannous Fluoride 0.40%<br/>           (0.15% w/v fluoride ion)</p> <p><b>Purpose</b><br/>           Anticavity/Sensitivity/<br/>           Antigingivitis</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• Aids in the prevention of caries</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> | <p><b>Warnings</b><br/>           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.</p> | <p>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.</p> <p><b>Directions</b><br/>           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</p> |

**Drug Facts (continued)**

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 on tube is broken or missing
- Keep tightly closed when not in use
- Store at controlled room temperature

**Inactive ingredients**  
 Acosulfame K, calcium sulfate, cocamidopropyl betaine, dimethicone, flavor, glycerin, lauryl sarcosine, monosodium phosphate, poloxamer 407, polyethylene glycol, pvm/ma copolymer, silica, sucralose

**Enamelon® Fluoride Toothpaste**

**Drug Facts**

**Active Ingredient**  
 Stannous Fluoride 0.45%  
 (0.16% w/v fluoride ion)

**Purpose**  
 Anticavity/Sensitivity/  
 Antigingivitis

**Uses**

- Aids in the prevention of caries
- 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 under 6 years of age. 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 2 years of age or older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

**Other information**

- 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 on tube is broken or missing
- Keep tightly closed when not in use
- Store at controlled room temperature

**Inactive ingredients**  
 Glycerin, polyethylene glycol, silica, pvm/ma copolymer, cocamidopropyl betaine, calcium sulfate, poloxamer 407, dimethicone, lauryl sarcosine, TiO<sub>2</sub>, flavor, acosulfame K, monosodium phosphate, sucralose

# 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      | 0.00400 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 MPAS AT 11%) (UNII: 5216HIHX5F) |          |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)   |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)  |          |
| GLYCERIN (UNII: PDC6A3C0OX)   |          |
| LAUROYL SARCOSINE (UNII: LIJ19P3L6F)  |          |
| SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)  |          |
| POLOXAMER 407 (UNII: TUF2IVW3M2)  |          |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)   |          |
| 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       |                      |                    |
| 1 |                  | 113 g in 1 TUBE     |                      |                    |

## 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)

**Establishment**

| Name                  | Address | ID/FEI    | Business Operations  |
|-----------------------|---------|-----------|--|
| Unicep Packaging, LLC |         | 790263909 | manufacture(48783-500) , pack(48783-500) , analysis(48783-500) |

Revised: 7/2014

Premier Dental Products Company