

**SENSODYNE PRONAMEL ACTIVE SHIELD FRESH MINT- potassium nitrate and sodium fluoride paste**  
**SENSODYNE PRONAMEL ACTIVE SHIELD COOL MINT- potassium nitrate and sodium fluoride paste**  
**Haleon US Holdings LLC**

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## ***Drug Facts***

### ***Active ingredient***

Potassium nitrate 5%

Sodium fluoride 0.25% (0.15% w/v fluoride ion)

### ***Purposes***

Antihypersensitivity

Anticavity

### ***Uses***

- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact.
- aids in the prevention of dental cavities.

### ***Warnings***

#### **Stop use and ask a dentist if**

- the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- pain/sensitivity still persists after 4 weeks of use.

#### **Keep out of reach of children.**

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

### ***Directions***

- **adults and children 12 years of age and older:**
  - apply at least a 1-inch strip of the product onto a soft bristle toothbrush.
  - brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.
- **children under 12 years of age:** Consult a dentist or doctor.

### ***Other information***

- do not store above 25°C (77°F)

### ***Inactive ingredients***

water, sorbitol, hydrated silica, glycerin, PEG-8, sodium lactate, flavor, xanthan gum, cocamidopropyl betaine, sodium methyl cocoyl taurate, titanium dioxide, sodium saccharin, PVM/MA copolymer, sodium hydroxide

### ***Questions or comments?***

**1-866-844-2797**

### ***Additional information (Fresh Mint)***

#### **SENSODYNE PRONAMEL ACTIVE SHIELD**

No 1 dentist recommended brand for enamel protection & strengthening.

Enamel is your natural defense shield for healthy teeth. Everyday it can be weakened by dietary or sugar acids which make your teeth more at risk to cavities and enamel wear.

New Pronamel Active Shield – start building resistance today to help keep your teeth strong and healthy for life.\*\*

Acids from foods, drinks or sugars weaken the enamel surface

Pronamel has a proven formula that actively reinforces weakened enamel

#### **Proven to actively reinforce weakened enamel**

Developed for defense against cavities and enamel wear by remineralizing your weakened enamel. Pronamel Active Shield helps with:

**2X stronger resistance against dietary acids from Day 1\***

**Helps shield the enamel against erosion and cavities**

**Enhanced foaming action# with extra fresh mint to leave the whole mouth feeling clean and fresh**

\*vs your mouth's natural defenses

\*\* With continued twice daily brushing, a healthy diet and regular dental visits.

#vs Pronamel Daily Protection

#### **ALWAYS FOLLOW THE LABEL**

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### ***Additional information (Cool Mint)***

## **S ENSODYNE PRONAMEL ACTIVE SHIELD**

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Enamel is your natural defense shield for healthy teeth. Everyday it can be weakened by dietary or sugar acids which make your teeth more at risk to cavities and enamel wear.

New Pronamel Active Shield – start building resistance today to help keep your teeth strong and healthy for life.\*\*

Acids from foods, drinks or sugars weaken the enamel surface

Pronamel has a proven formula that actively reinforces weakened enamel

### **Proven to actively reinforce weakened enamel**

Developed for defense against cavities and enamel wear by remineralizing your weakened enamel. Pronamel Active Shield helps with:

**2X stronger resistance against dietary acids from Day 1\***

**Helps shield the enamel against erosion and cavities**

**Enhanced foaming action# with extra fresh mint to leave the whole mouth feeling clean and fresh**

**Effectively and gently removes stains for whiter teeth**

\*vs your mouth's natural defenses

\*\* With continued twice daily brushing, a healthy diet and regular dental visits.

#vs Pronamel Daily Protection

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## **Principal Display Panel**

**SENSODYNE**

**PRONAMEL ACTIVE SHIELD**

**TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION**

**FRESH MINT**

**Builds Enamel Resistance**

**For Cavity & Erosion Protection**

NET WT 3.4 OZ (96.4 g)

62000000200006 – Front Carton



**Principal Display Panel**

**SENSODYNE**

**PRONAMEL**

**ACTIVE SHIELD**

**TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION**

**COOL MINT WHITENING**

**Builds Enamel Resistance**

**For Cavity & Erosion Protection**

NET WT 3.4 OZ (96.4 g)

620000000200004 - Front Carton



**SENSODYNE PRONAMEL ACTIVE SHIELD FRESH MINT**

potassium nitrate and sodium fluoride paste

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0700
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.15 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>SODIUM METHYL COCOYL TAURATE</b> (UNII: JVL98CG53G)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0700-01	1 in 1 CARTON	01/02/2023	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0700-02	23 g in 1 TUBE; Type 0: Not a Combination Product	01/02/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/02/2023	

## SENSODYNE PRONAMEL ACTIVE SHIELD COOL MINT

potassium nitrate and sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0701
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.15 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>SODIUM METHYL COCOYL TAURATE</b> (UNII: JVL98CG53G)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0701-01	1 in 1 CARTON	01/02/2023	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0701-02	1 in 1 CARTON	01/02/2023	
2		65.2 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0135-0701-03	2 in 1 CARTON	01/02/2024	
3		96.4 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 Drug	M022	01/02/2023	

**Labeler** - Haleon US Holdings LLC (079944263)

Revised: 3/2024

Haleon US Holdings LLC