

SENSODYNE PRONAMEL STRONG AND BRIGHT ENAMEL MINT- potassium nitrate and sodium fluoride paste
SENSODYNE PRONAMEL STRONG AND BRIGHT ENAMEL EXTRA FRESH- potassium nitrate and sodium fluoride paste
Haleon US Holdings LLC

Drug Facts

Active ingredients

Potassium nitrate 5%

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

Purpose

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

When using this product,

if irritation occurs discontinue use.

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
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	(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	Consult a dentist or doctor.

Other information

store below 25°C (77°F)

Inactive ingredients

water, hydrated silica, sorbitol, glycerin, PEG-8, flavor, cocamidopropyl betaine, titanium dioxide, xanthan gum, sodium saccharin, sodium hydroxide

Questions or comments?

Call toll-free **1-866-844-2797**

Principal Display Panel

NDC 0135-0602-01

SENSODYNE

PRONAMEL

STRONG & Bright

ENAMEL

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

STRONGENAMEL

WHITERTEETH*

MINT

No. 1 DENTIST RECOMMENDED BRAND

FOR STRENGTHENING AND PROTECTING ENAMEL

*vs. ProNamel Daily Protection

NET WT 3.0 OZ (85 g)

Enamel is the vital layer of protection for your teeth and keeping it strong is so important.

Sensodyne ProNamel STRONG & BrightENAMEL gives you whiter teeth* while actively helping to strengthen your tooth enamel and protect against everyday acids.

*vs. ProNamel Daily Protection

With twice daily brushing, the dual action formulation:

- **Delivers minerals into the enamel to help STRENGTHEN & PROTECT.**
- **Polishes away stains for WHITER BRIGHTER TEETH.**

FRESHENS breath and fights **CAVITIES**

GSK Consumer Healthcare

Warren, NJ 07059

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ALWAYS FOLLOW THE LABEL

105491XC



Principal Display Panel

NDC 0135-0603-01

SENSODYNE

PRONAMEL

STRONG & Bright

ENAMEL

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

STRONG ENAMEL

WHITER TEETH*

EXTRA FRESH

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ALWAYS FOLLOW THE LABEL

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NDC 0135-0603-01



NET WT 3.0 OZ (85 g)



TOOTH PASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

STRONG ENAMEL WHITER TEETH*

EXTRA FRESH

*vs. ProNamel Daily Protection




FOR STRENGTHENING AND PROTECTING ENAMEL

SENSODYNE PRONAMEL STRONG AND BRIGHT ENAMEL MINT

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0602
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0602-01	1 in 1 CARTON	12/19/2016	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0602-02	1 in 1 CARTON	12/19/2016	
2		23 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	12/19/2016	

SENSODYNE PRONAMEL STRONG AND BRIGHT ENAMEL EXTRA FRESH

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0603
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

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Color	white	Score	
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1		85 g in 1 TUBE; Type 0: Not a Combination Product		

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Labeler - Haleon US Holdings LLC (079944263)