

**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**

**GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

*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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## **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***

<b>Adults and children 12 years of age and older:</b>	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
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	by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.
<b>Children under 12 years</b>	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**

**STRONG ENAMEL**

**WHITER TEETH\***

**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 & Bright ENAMEL** 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\*

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GSK Consumer Healthcare

Warren, NJ 07059

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105488XC



TOOTHPASTE FOR SENSITIVE  
TEETH AND CAVITY PREVENTION

**STRONG ENAMEL  
WHITER TEETH\***

**EXTRA FRESH**

\*vs. ProNamel  
Daily Protection



## SENSODYNE PRONAMEL STRONG AND BRIGHT ENAMEL MINT

potassium nitrate and sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0602
<b>Route of Administration</b>	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: 5OCF3011KX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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 not final	part356	12/19/2016	

## SENSODYNE PRONAMEL STRONG AND BRIGHT ENAMEL EXTRA FRESH

potassium nitrate and sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0603
<b>Route of Administration</b>	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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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)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 12/2020

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC