

SENSODYNE PRONAMEL GENTLE WHITENING ADVANCED- 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)

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

Questions or comments?

1-866-844-2797

Additional information

ALWAYS FOLLOW THE LABEL

SENSODYNE PRONAMEL

Does not contain: SLS/sulfates • artificial dyes • parabens • triclosan • peroxide

Acidic foods and drinks can cause enamel loss that can lead to yellowing, dullness and sensitivity. Pronamel has a specialty formulation to help rebuild and restore acid weakened enamel, helping prevent enamel loss for strong, healthy teeth.

ACID ATTACKS ENAMEL

WEAKENING THE ENAMEL STRUCTURE

PRONAMEL REBUILDS & RESTORES ENAMEL

FOR STRONG HEALTHY TEETH

Healthy white teeth start with strong enamel.

Pronamel has a proven specialist technology that has been developed to maximize the effect of fluoride on enamel.

With twice-daily brushing, Pronamel helps to:

- Rebuild enamel strength for strong, healthy teeth
- Protect against the effects of dietary acids
- Relieve sensitive teeth
- Freshen breath
- Protect against cavities

Recyclable Carton Save Water

Turn off tap while brushing

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GSK Consumer Healthcare

Warren, NJ 07059

Principal Display Panel

NDC 0135-0580-01

SENSODYNE

PRONAMEL

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

GENTLE WHITENING

ADVANCED

Specialist Enamel Protection

Rebuilds, Restores, Refreshes

NET WT 6.5 OZ (184 g)

62000000069596 Front Carton



SENSODYNE PRONAMEL GENTLE WHITENING ADVANCED

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0580
Route of Administration	DENTAL		

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

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0580-01	1 in 1 CARTON	03/15/2021	
1		184 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0580-02	4 in 1 CARTON	07/01/2023	
2		184 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	03/15/2021	

Labeler - Haleon US Holdings LLC (079944263)

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Haleon US Holdings LLC