SENSODYNE PRONAMEL CLINICAL ENAMEL STRENGTH WHITENING ACTION-potassium nitrate, 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, sorbitol, hydrated silica, glycerin, PEG-8, sodium lactate, flavor, cocamidopropyl betaine, xanthan gum, silica, titanium dioxide, sodium saccharin, PVM/MA copolymer, sodium hydroxide

Questions or comments?

1-866-844-2797

ALWAYS FOLLOW THE LABEL

Principal Display Panel

NEW HALEON

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

SENSODYNEPRONAMEL

CLINICAL ENAMEL STRENGTH

3X STRONGER ENAMEL PROTECTION*

1 DENTIST RECOMMENDED BRAND FOR ENAMEL EROSION

WHITENING ACTION

NET WT 2.3 OZ (65.2 g)

62000000211437 – Front Carton

SENSODYNE PRONAMEL CLINICAL ENAMEL STRENGTH WHITENING ACTION

potassium nitrate, sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0811
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)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL VINYL ETHER AND MALEIC ACID COPOLYMER (LOW MOLECULAR WEIGHT) (UNII: R2PDK4MI4R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT (Cool)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0811-03	1 in 1 CARTON	01/06/2025	
1		65.2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0811-02	1 in 1 CARTON	01/06/2025	
2		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0135-0811-23	2 in 1 CARTON	12/01/2025	
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	01/06/2025	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 10/2025 Haleon US Holdings LLC