SENSODYNE- potassium nitrate and sodium fluoride paste Haleon US Holdings LLC

Drug Facts

Active ingredients

Potassium nitrate 5%

Sodium fluoride 0.25% (0.16% 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

• store below 30°C (86°F)

Inactive ingredients

water, hydrated silica, sorbitol, glycerin, pentasodium triphosphate, PEG-8, sodium lauryl sulfate, flavor, xanthan gum, sodium hydroxide, cocamidopropyl betaine, sodium saccharin, blue 1

Questions or comments?

1-866-844-2797

Additional Information

ALWAYS FOLLOW THE LABEL

What are sensitive teeth?

Lots of people have sensitive teeth. When enamel is worn away (through eating everyday acidic food or drinks) or gums recede, the dentin underneath becomes exposed. This can lead to tooth sensitivity, for example, with cold and hot food and drinks.

What does Sensodyne do?

Sensodyne provides daily care for sensitive teeth* plus all the benefits you would expect from a daily fluoride toothpaste – strong teeth and freshness.

*with twice dai ly brushing

24/7 Sensitivity Protection*

+ Strong & Healthy Teeth

Exposed Dentin

Use Sensodyne Deep Clean + Whitening twice daily:

- Long lasting sensitivity protection* every day
- Contains fluoride to protect against cavities

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Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

Principal Display Panel

NDC 0135-0593-01

#1 DENTIST RECOMMENDED BRAND

SENSODYNE

Deep Clean + Whitening

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

24/7 Sensitivity Protection* + Strong & Healthy Teeth

NET WT 4.0 OZ (113 g)

6200000053546



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: 059QF0K00R)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
SORBITOL (UNII: 506T60A25R)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
XANTHAN GUM (UNII: TTV12P4NEE)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				

P	roduct Chara	cteristics				
Color		blue	Score			
Shape			Size			
Flavor			Imprint Code			
Сс	ontains					
Pa	ackaging					
#	ltem Code	Package Description		Marketing Start Date	Marketing End Date	
1	NDC:0135-0593- 01	L in 1 CARTON			12/19/2016	
1		113 g in 1 TUBE; Type 0: Not a Combination Product				
2	NDC:0135-0593- 02	1 in 1 CARTON			12/19/2016	07/31/2019
2		23 g in 1 TUBE; ⁻ Product	Type 0: Not a C	ombination		
M	larketing I	nformatio	on			
	Marketing Category	Applicatio	on Number of Citation	r Monograph	Marketing Start Date	Marketing End Date
	FC Monograph Drug	a M022			12/19/2016	

Labeler - Haleon US Holdings LLC (079944263)

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Haleon US Holdings LLC