

SENSODYNE- 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.

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 daily 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)

62000000053546

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#1 DENTIST RECOMMENDED BRAND

SENSODYNE

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

24/7 Sensitivity Protection* + Strong & Healthy Teeth

**Deep Clean
+ Whitening**

NET WT 4.0 OZ (113 g)

SENSODYNE

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0593
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:Q80VPU408O)	FLUORIDE ION	1.15 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
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: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0593-01	1 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; 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	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 11/2021

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC