

**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 0.24% (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

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, flavor, titanium dioxide, cocamidopropyl betaine, sodium methyl cocoyl taurate, xanthan gum, sodium hydroxide, sodium saccharin, sucralose

Questions or comments?

1-866-844-2797

Additional Information (Full Protection)

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.

Exposed Dentin

24/7 Sensitivity Protection*

+ Strong & Healthy Teeth

Use Sensodyne Full Protection

+ 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

Additional Information (Tartar Control)

Use Sensodyne Tartar Control

+ Whitening twice daily:

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

Principal Display Panel

NDC 0135-0550-04

#1 DENTIST RECOMMENDED BRAND

SENSODYNE

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

24/7 SENSITIVITY PROTECTION* + Strong & Healthy Teeth

Full Protection + Whitening

NET WT 4.0 OZ (113 g)

62000000053366

NDC 0135-0550-04

#1 DENTIST RECOMMENDED BRAND

SENSODYNE

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

24/7 Sensitivity Protection* + Strong & Healthy Teeth

gsk

**Full
Protection
+ Whitening**

NET WT 4.0 OZ (113 g)

Principal Display Panel

NDC 0135-0551-04

#1 DENTIST RECOMMENDED BRAND

SENSODYNE

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

24/7 SENSITIVITY PROTECTION* + Strong & Healthy Teeth

Tartar Control + Whitening

NET WT 4.0 OZ (113 g)

62000000053367

NDC 0135-0551-04

#1 DENTIST RECOMMENDED BRAND

SENSODYNE

TOOTH PASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

24/7 Sensitivity Protection* + Strong & Healthy Teeth



SENSODYNE

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0550
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	1.1 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)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:0135-0550-04	1 in 1 CARTON	02/17/2004	
1		113 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	02/17/2004	

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0551-04	1 in 1 CARTON	01/02/2002	
1		113 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	01/02/2002	

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

Revised: 3/2022

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC