

**SENSODYNE EXTRA WHITENING COOL MINT- potassium nitrate and sodium fluoride paste**

**Haleon US Holdings LLC**

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***Drug Facts***

***Active ingredients***

Potassium nitrate 5%

Sodium fluoride 0.24% (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, pentasodium triphosphate, PEG-8, flavor, cocamidopropyl betaine, sodium methyl cocoyl taurate, titanium dioxide, xanthan gum, sodium hydroxide, sodium saccharin

## ***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.

#### **Exposed Dentin**

**24/7**

#### **Sensitivity Protection\***

**+ Strong & Healthy Teeth**

#### **Use Sensodyne Extra Whitening**

#### **Cool Mint twice daily:**

- Long lasting sensitivity protection\* everyday
- Contains fluoride to protect against cavities

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Warren, NJ 07059

## **Principal Display Panel**

**SENSODYNE**

**#1 DENTIST RECOMMENDED BRAND**

# TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

24/7 Sensitivity Protection\* + Strong & Healthy Teeth

**Extra Whitening**

**Cool Mint**

NET WT 4.0 OZ (113 g)

62000000079742 Front Carton



## SENSODYNE EXTRA WHITENING COOL MINT

potassium nitrate and sodium fluoride paste

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0135-0643 |
| <b>Route of Administration</b> | DENTAL         |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength       |
|---|-------------------|----------------|
| <b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) | POTASSIUM NITRATE | 50 mg in 1 g   |
| <b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)  | FLUORIDE ION      | 1.15 mg in 1 g |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                             |          |
| <b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)                   |          |
| <b>SORBITOL</b> (UNII: 506T60A25R)                          |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                          |          |
| <b>SODIUM TRIPOLYPHOSPHATE ANHYDROUS</b> (UNII: 9SW4PFD2FZ) |          |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)           |          |
| <b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)            |          |
| <b>SODIUM METHYL COCOYL TAURATE</b> (UNII: JVL98CG53G)      |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                  |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                       |          |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)                  |          |

**SACCHARIN SODIUM** (UNII: SB8ZUX40TY)

### Product Characteristics

|                 |             |                     |  |
|-----------------|-------------|---------------------|--|
| <b>Color</b>    | white       | <b>Score</b>        |  |
| <b>Shape</b>    |             | <b>Size</b>         |  |
| <b>Flavor</b>   | MINT (Cool) | <b>Imprint Code</b> |  |
| <b>Contains</b> |             |                     |  |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0135-0643-01 | 1 in 1 CARTON                                      | 04/03/2023           |                    |
| 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 Drug | M022                                     | 04/03/2023           |                    |

**Labeler** - Haleon US Holdings LLC (079944263)

Revised: 3/2024

Haleon US Holdings LLC