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

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## **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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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   | <b>Basis of Strength</b> | Strength       |  |  |  |  |
| <b>POTASSIUM NITRATE</b> (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<br>Date | Marketing End<br>Date   |                       |
| 1      | NDC:0135-0593-<br>01  | L in 1 CARTON   |                          |                         | 12/19/2016              |                       |
| 1      |                       | 113 g in 1 TUBE; Type 0: Not a Combination<br>Product |                          |                         |                         |                       |
| 2      | NDC:0135-0593-<br>02  | 1 in 1 CARTON   |                          |                         | 12/19/2016              | 07/31/2019            |
| 2      |                       | 23 g in 1 TUBE; <sup>-</sup><br>Product               | Type 0: Not a C          | ombination              |                         |                       |
|        |                       |   |                          |                         |                         |                       |
| M      | larketing I           | nformatio   | on                       |                         |                         |                       |
|        | Marketing<br>Category | Applicatio  | on Number of<br>Citation | r Monograph             | Marketing Start<br>Date | Marketing End<br>Date |
|        | FC Monograph Drug     | a M022  |                          |                         | 12/19/2016              |                       |

# Labeler - Haleon US Holdings LLC (079944263)

Revised: 1/2024

Haleon US Holdings LLC