SENSODYNE REPAIR AND PROTECT- stannous fluoride paste SENSODYNE REPAIR AND PROTECT EXTRA FRESH- stannous fluoride paste SENSODYNE REPAIR AND PROTECT WHITENING- stannous fluoride paste Haleon US Holdings LLC

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# **Drug Facts**

# Active ingredient

Stannous fluoride 0.454% (0.15% w/v fluoride ion)

## **Purposes**

Anticavity, Antihypersensitivity

#### Uses

- aids in the prevention of dental cavities.
- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact.

# 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

• products containing stannous fluoride may product surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or

permanent and may be removed by your dentist.

- this product is specifically formulated to help prevent staining.
- store above 30°C (86°F)

## Inactive ingredients (Mint)

glycerin, PEG-8, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, polyacrylic acid, silica, cocamidopropyl betaine, sodium saccharin

# Inactive ingredients (Extra Fresh)

glycerin, PEG-8, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, polyacrylic acid, silica, sodium saccharin, cocamidopropyl betaine

# Inactive ingredients (Whitening)

glycerin, PEG-8, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, polyacrylic acid, silica, cocamidopropyl betaine, sodium saccharin

#### Questions or comments?

1-866-844-2797

#### Other Information

## SENSODYNE REPAIR & PROTECT DEEP REPAIR

**Sensodyne Repair & Protect**has a clinically proven ingredient. With twice daily brushing it helps to repair deep inside the tubules and relieves sensitivity to help you enjoy life without worrying about the pain of sensitive teeth.

EXPOSED DENTIN; CAUSE OF SENSITIVE TEETH

**TINY HOLES** 

GETS DEEP INSIDE THESE HOLES

TO HELP REPAIR THESE HOLES

WHICH HELPS PROTECT FROM PAIN\*

Daily use fluoride toothpaste to provide long lasting sensitivity relief, whilst also keeping your teeth and gums healthy. \*

\*with twice daily brushing

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Distributed by: Haleon, Warren, NJ 07059

Pat. Info www.productpats.com

†Recycling facilities for this product may not exist in your area

**CARTON**RECYCLE

**TUBE**RECYCLE

**CAP**CHECK LOCALLY†

# **Principal Display Panel (Mint)**

#1 DENTIST RECOMMENDED BRAND

#### SENSODYNE

#### FLUORIDE TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

MINT

**REPAIR & PROTECT** 

**DEEP REPAIR** 

**NET WT 3.4 OZ (96.4 g)** 

62000000207021



# **Principal Display Panel (Extra Fresh)**

#1 DENTIST RECOMMENDED BRAND

#### SENSODYNE

FLUORIDE TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

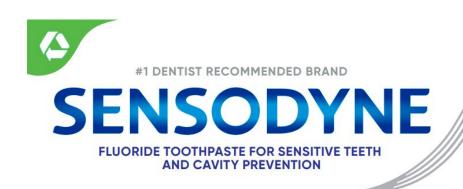
**EXTRA FRESH** 

**REPAIR & PROTECT** 

**DEEP REPAIR** 

**NET WT 3.4 OZ (96.4 g)** 

62000000207114





# **Principal Display Panel (Whitening)**

#1 DENTIST RECOMMENDED BRAND

#### **SENSODYNE**

FLUORIDE TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

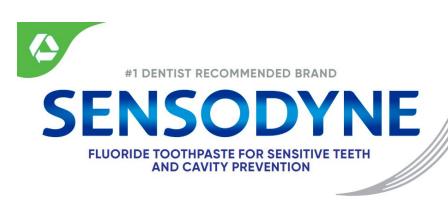
WHITENING

**REPAIR & PROTECTED** 

**DEEP REPAIR** 

**NET WT 3.4 OZ (96.4 g)** 

62000000207026





## SENSODYNE REPAIR AND PROTECT

stannous fluoride paste

| Dro   | duct | Information  |
|-------|------|--------------|
| T I U | uuct | minomination |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0135-0548

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION

1.1 mg in 1 g

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| GLYCERIN (UNII: PDC6A3C0OX)                                  |          |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)                   |          |
| HYDRATED SILICA (UNII: Y6O7T4G8P9)                           |          |
| SODIUM TRIPOLYPHOSPHATE, UNSPECIFIED FORM (UNII: 5HK03SA80J) |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                     |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                           |          |
| COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)                    |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                          |          |

| <b>Product Characteristics</b> |       |              |
|--------------------------------|-------|--------------|
| Color                          | white | Score        |
| Shape                          |       | Size         |
| Flavor                         | MINT  | Imprint Code |
| Contains                       |       |              |

| P | Packaging            |   |                         |                       |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code            | Package Description                                 | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:0135-0548-<br>02 | 1 in 1 CARTON                                       | 06/28/2021              |                       |
| 1 |                      | 96.4 g in 1 TUBE; Type 0: Not a Combination Product |                         |                       |
| 2 | NDC:0135-0548-<br>01 | 1 in 1 CARTON                                       | 06/28/2021              |                       |
| 2 |                      | 23 g in 1 TUBE; Type 0: Not a Combination Product   |                         |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | M022  | 06/28/2021              |                       |
|                       |   |                         |                       |

# SENSODYNE REPAIR AND PROTECT EXTRA FRESH

stannous fluoride paste

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0547 |
| Route of Administration | ORAL           |                    |               |
|                         |                |                    |               |

# **Active Ingredient/Active Moiety**

COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)

## **Ingredient Name**

**Basis of Strength** Strength

STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION

1.1 mg in 1 g

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| GLYCERIN (UNII: PDC6A3C0OX)                                  |          |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)                   |          |
| HYDRATED SILICA (UNII: Y6O7T4G8P9)                           |          |
| SODIUM TRIPOLYPHOSPHATE, UNSPECIFIED FORM (UNII: 5HK03SA80J) |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                     |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                           |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                          |          |

| <b>Product Characteristics</b> |       |              |  |
|--------------------------------|-------|--------------|--|
| Color                          | white | Score        |  |
| Shape                          |       | Size         |  |
| Flavor                         | MINT  | Imprint Code |  |
| Contains                       |       |              |  |

| P | ackaging             |   |                         |                       |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code            | Package Description                                 | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:0135-0547-<br>02 | 1 in 1 CARTON                                       | 06/28/2021              |                       |
| 1 |                      | 96.4 g in 1 TUBE; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | M022  | 06/28/2021              |                       |
|                       |   |                         |                       |

# SENSODYNE REPAIR AND PROTECT WHITENING

stannous fluoride paste

| <b>Product Information</b> |                |                    |               |
|----------------------------|----------------|--------------------|---------------|
| Product Type               | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0575 |
| Route of Administration    | ORAL           |                    |               |
|                            |                |                    |               |

# Active Ingredient/Active Moiety Ingredient Name

**Basis of Strength** Strength

STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION

1.1 mg in 1 g

# **Inactive Ingredients**

| mactive mgredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| GLYCERIN (UNII: PDC6A3C0OX)                                  |          |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)                   |          |
| HYDRATED SILICA (UNII: Y6O7T4G8P9)                           |          |
| SODIUM TRIPOLYPHOSPHATE, UNSPECIFIED FORM (UNII: 5HK03SA80J) |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                     |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                          |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                           |          |
| COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)                    |          |
|  |          |

| Pr | oduct | Characteristics |
|----|-------|-----------------|
|    |       |                 |

**SACCHARIN SODIUM** (UNII: SB8ZUX40TY)

| Color    | white | Score        |  |
|----------|-------|--------------|--|
| Shape    |       | Size         |  |
| Flavor   | MINT  | Imprint Code |  |
| Contains |       |              |  |

**Packaging** 

| # | Item Code            | Package Description                                 | Marketing Start<br>Date | Marketing End<br>Date |
|---|----------------------|---|-------------------------|-----------------------|
| 1 | NDC:0135-0575-<br>01 | 1 in 1 CARTON                                       | 06/28/2021              |                       |
| 1 |                      | 96.4 g in 1 TUBE; Type 0: Not a Combination Product |                         |                       |

# **Marketing Information**

| Marketing          | Application Number or Monograph | Marketing Start | Marketing End |
|--------------------|---------------------------------|-----------------|---------------|
| Category           | Citation                        | Date            | Date          |
| OTC Monograph Drug | M022                            | 06/28/2021      |               |

# Labeler - Haleon US Holdings LLC (079944263)

Revised: 3/2024 Haleon US Holdings LLC