

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

**SENSODYNE FRESH MINT- potassium nitrate and sodium fluoride paste**

**SENSODYNE FRESH IMPACT- potassium nitrate and sodium fluoride paste**

**Haleon US Holdings LLC**

-----

## ***Drug Facts***

### ***Active ingredients***

Potassium nitrate (5%)

Sensodyne Fresh Mint, and Fresh Impact: Sodium fluoride 0.25% (0.15% w/v fluoride ion)

Sensodyne Extra Whitening: 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.

### ***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 (Extra Whitening)***

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

### ***Inactive ingredients (Fresh Mint)***

water, sorbitol, hydrated silica, glycerin, cocamidopropyl betaine, flavor, xanthan gum, titanium dioxide, sodium saccharin, sodium hydroxide, sucralose, yellow 10, blue 1

### ***Inactive ingredients (Fresh Impact)***

water, sorbitol, hydrated silica, glycerin, cocamidopropyl betaine, flavor, xanthan gum, titanium dioxide, sodium saccharin, sodium hydroxide, sucralose, blue 1

### ***Questions or comments?***

**1-866-844-2797**

### **Additional Information**

#### **ALWAYS FOLLOW THE LABEL**

Trademarks are owned by or licensed to the GSK group of companies.

©2020 GSK group of companies or its licensor.

Distributed by:

#### **GSK Consumer Healthcare**

Warren, NJ 07059

### **Principal Display Panel**

**NDC 0135-0525-04**

#1 DENTIST RECOMMENDED BRAND

**SENSODYNE**

**Extra Whitening**

**TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION**

## 24/7 SENSITIVITY PROTECTION\* + **Strong & Healthy Teeth**

### **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**

### **Use Sensodyne Extra Whitening twice daily:**

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

NET WT 4.0 OZ (113g)

53371 Front Carton



### **Principal Display Panel**

**NDC 0135-0529-04**

#1 Dentist Recommended Brand

**SENSODYNE**

**Fresh Mint**

**TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION**

24/7 SENSITIVITY PROTECTION\* + **Strong & Healthy Teeth**

NET WT 4.0 OZ (113g)

### **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**

#### **Use Sensodyne Fresh Mint twice daily:**

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

6209 Front Carton



### **Principal Display Panel**

**NDC 0135-0528-04**

#1 Dentist Recommended Brand

**SENSODYNE**

**Fresh Impact**

**TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION**

**24/7 SENSITIVITY PROTECTION\* + Strong & Healthy Teeth**

NET WT 4.0 OZ (113g)

### **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

Use Sensodyne Fresh Impact twice daily:

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

6191 Front Carton



## SENSODYNE EXTRA WHITENING

potassium nitrate and sodium fluoride paste

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0525
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	1.11 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM TRIPOLYPHOSPHATE, UNSPECIFIED FORM (UNII: 5HK03SA80J)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>SODIUM METHYL COCOYL TAURATE</b> (UNII: JVL98CG53G)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0525-03	2 in 1 CARTON	09/30/1990	
1		1 in 1 CARTON		
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0525-04	1 in 1 CARTON	09/30/1990	
2		113 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0135-0525-05	1 in 1 CARTON	09/30/1990	
3		77 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0135-0525-06	1 in 1 CARTON	09/30/1990	
4		170 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:0135-0525-07	1 in 1 CARTON	09/30/1990	
5		23 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:0135-0525-11	3 in 1 CARTON	09/30/1990	
6		1 in 1 CARTON		
6		184 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:0135-0525-13	4 in 1 CARTON	06/23/2016	
7		184 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:0135-0525-08	1 in 1 CARTON	07/01/2019	
8		184 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:0135-0525-14	4 in 1 CARTON	07/01/2023	
9		184 g in 1 TUBE; Type 0: Not a Combination		

9	Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M022	09/30/1990	

<b>SENSODYNE FRESH MINT</b>			
potassium nitrate and sodium fluoride paste			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0529
<b>Route of Administration</b>	DENTAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<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
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)			
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)			
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)			
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)			
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)			
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)			
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)			
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)			
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)			
<b>WATER</b> (UNII: 059QF0KO0R)			
<b>SORBITOL</b> (UNII: 506T60A25R)			
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)			
<b>Product Characteristics</b>			
<b>Color</b>	green	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			
<b>Packaging</b>			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0529-03	2 in 1 CARTON	12/16/2014	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0529-04	1 in 1 CARTON	09/30/1990	
2		113 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0135-0529-05	1 in 1 CARTON	09/30/1990	
3		77 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0135-0529-01	1 in 1 CARTON	01/14/2019	
4		23 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:0135-0529-10	23 g in 1 TUBE; Type 0: Not a Combination Product	01/02/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	09/30/1990	

## SENSODYNE FRESH IMPACT

potassium nitrate and sodium fluoride paste

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0528
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:Q80VPU4080)	FLUORIDE ION	1.15 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	



<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

### Product Characteristics

<b>Color</b>	white (white and blue)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0528-04	1 in 1 CARTON	07/01/2000	
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	07/01/2000	

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