

**FRESHMINT SENSITIVE- potassium nitrate and sodium fluoride paste, dentifrice**

**New World Imports, Inc**

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**Drug Facts**

**Active Ingredients**

Potassium Nitrate - 5%

Sodium Fluoride - 0.24%

**Purpose**

Potassium Nitrate - Antihypersensitivity

Sodium Fluoride - Anticavity

**Keep out of reach of Children**

If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.

**Uses**

Builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact.

Aids in the prevention of dental cavities

**Warnings**

**Stop and ask a dentist if**

- The problem persists or worsens. Sensitive teeth may indicate a serious problem that may require prompt care by a dentist
- Pain / sensitivity still persists after 4 weeks of use

**Directions**

**Adults and children 12 years 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), or as recommended by your dentist. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing

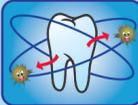
**Children under 12 years of age:**consult a doctor.

## Inactive Ingredients

Sorbitol, Silica, Treated Water, PEG-32, Sodium Lauryl Sulfate, Glycerin, Flavor, Cellulose Gum, Titanium Dioxide, Trisodium Phosphate, Sodium Saccharin, Sodium Benzoate, Color: D and C Yellow # 10, FD and C Blue # 1.

<b>Drug Facts</b> <b>Active Ingredients</b> Potassium Nitrate - 5%..... Antihypersensitivity Sodium Fluoride - 0.24% (0.15% w/v fluoride ion) ..... Anticavity <b>Uses</b> <ul style="list-style-type: none"> <li>builds increasing protection against painful sensitivity of the teeth due to cold, heat, acids, sweets or contact</li> <li>aids in the prevention of dental cavities</li> </ul>		<b>Drug Facts (Continued)</b> <b>Warnings</b> Stop and ask a dentist if <ul style="list-style-type: none"> <li>the problem persists or worsens. Sensitive teeth may indicate a serious problem that may require prompt care by a dentist.</li> <li>pain / sensitivity still persists after 4 weeks of use</li> </ul>		
<b>Drug Facts (Continued)</b> <b>Keep out of reach of children.</b> If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately. <b>Directions</b> <ul style="list-style-type: none"> <li><b>Adults and children 12 years of age and older:</b> <ul style="list-style-type: none"> <li>apply at least a 1-inch strip of the product onto a soft bristle toothbrush.</li> </ul> </li> </ul>		<b>Drug Facts (Continued)</b> <ul style="list-style-type: none"> <li>brush teeth thoroughly for at least 1 minute twice a day (morning and evening), or as recommended by your dentist. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.</li> <li><b>children under 12 years of age:</b> Consult a dentist or doctor.</li> </ul> <b>Other Information</b> ← Store between 15° to 25°C (59° to 77°F) <b>Inactive Ingredients</b> ← Sorbitol, Silica, Treated Water, PEG-32, Sodium Lauryl Sulfate, Glycerin, Flavor, Cellulose Gum, Titanium Dioxide, Trisodium Phosphate, Sodium Saccharin, Sodium Benzoate, D&C Yellow #10, FD&C Blue # 1		
Distributed by: NWI, Inc., 160 Athens Way, Nashville, TN 37228 www.nwiinc.com NDC # 51824-053-01 *This product is not manufactured or distributed by Haleon US Holdings LLC, owner of the register trademark Sensodyne®				





Aids in Cavity Prevention



Helps to Reduce Sensitivity



Helps Mouth Feel Fresh & Clean



Protection Against Painful Sensitivity and Anti-Cavity Prevention

NET WT. 4.3 OZ (122g)

\*Compare to the Active Ingredients of Sensodyne® Fresh Mint

## FRESHMINT SENSITIVE

potassium nitrate and sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51824-053
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.4 mg in 1 g
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL 1600</b> (UNII: 1212Z7S33A)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE</b> (UNII: B70850QPHR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Product Characteristics

<b>Color</b>	green (Mint Green)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-053-02	1 in 1 BOX	09/16/2010	
1	NDC:51824-053-01	122 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	m021	09/16/2010	

**Labeler** - New World Imports, Inc (075372276)

