

**FRESHMINT PREMIUM ANTICAVITY GEL- sodium fluoride paste, dentifrice**  
**New World Imports, Inc**

-----  
**OTC Active Ingredient**

Sodium Fluoride - 0.243% (0.15 w/v fluoride ion)

**OTC Purpose**

Anticavity

**Keep out of reach of Children under 6 years of age**

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

**Uses**

Helps protect teeth and roots against cavities.

**Warnings**

**Keep out of reach of children under 6 years of age.** if you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.

**Directions**

Adults and children 2 years & older:

- Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist.
- Do not swallow.
- To minimize swallowing use a pea-sized amount in children under 6 years of age.
- Supervise children's brushing until good habits are established.

Children under 2 years:

- Ask a dentist

**Inactive Ingredients**

Sorbitol, Silica, Treated Water, Polyethylene Glycol 1500, Sodium Lauryl Sulfate, Glycerin, Flavor, Cellulose Gum, Sodium Benzoate, Sodium Saccharin, Trisodium Phosphate, Methylparaben, Tetrasodium Pyrophosphate, Propylparaben, FD&C Blue # 1

**ADA**  
Accepted  
American Dental Association

• Helps prevent cavities

No Animal Based Ingredients

**freshmint**<sup>®</sup>  
Premium Fluoride Anticavity Gel Toothpaste

NET WT. 1 OZ

<b>DRUG FACTS:</b>	
<b>ACTIVE INGREDIENT:</b> Sodium Fluoride - 0.243% w/w (Fluoride ion content: 1100 ppm)...	<b>PURPOSE:</b> Anticavity
<b>USES:</b> Helps protect teeth and roots against cavities.	
<b>WARNINGS:</b> Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.	
<b>DIRECTIONS:</b> • Adults and children 2 years & older: Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. Do not swallow. To minimize swallowing use a pea-sized amount in children under 6 years of age. Supervise children's brushing until good habits are established. • Children under 2 years: Ask a dentist.	
<b>INACTIVE INGREDIENTS:</b> Sorbitol, Silica, Treated Water, Polyethylene Glycol 1500, Sodium Lauryl Sulfate, Glycerin, Flavor, Cellulose Gum, Sodium Benzoate, Sodium Saccharin, Trisodium Phosphate, Methylparaben, Tetrasodium Pyrophosphate, Propylparaben, FD&C Blue # 1.	

Product of India,  
Exclusive Distributor: NWI, Inc., 160 Athens Way, Nashville, TN 37228

Exp. Date & Batch No. on crimp.

XXXXXXXXXX

**FRESHMINT PREMIUM ANTICAVITY GEL**

sodium fluoride paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51824-046
<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	2.43 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 1500</b> (UNII: 1212Z7S33A)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE</b> (UNII: B70850QPHR)
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)

### Product Characteristics

<b>Color</b>	blue (Aqua 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:51824-046-02	144 in 1 CARTON	01/01/2015	
1	NDC:51824-046-01	28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51824-046-04	72 in 1 CARTON	01/01/2015	
2	NDC:51824-046-03	85 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	01/01/2015	

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