

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

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**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**

Aids in the prevention of dental 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.
- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing, use a pea-sized amount)
- Supervise children's brushing until good habits are established.

**Children under 2 years:**

- Consult a dentist or doctor

**Inactive Ingredients**

Sorbitol, Silica, Treated Water, Glycerin, PEG-32, Sodium Lauryl Sulfate, Flavor, Titanium Dioxide, Cellulose Gum, Carrageenan, Trisodium Phosphate, Sodium Saccharin, Sodium Benzoate, Tetrasodium Pyrophosphate, FD&C Blue #1



# freshmint®

Premium Anticavity Fluoride Toothpaste

NET WT. 3.0 OZ

|   |                 |   |  |
|---|-----------------|---|--|
| <b>DRUG FACTS:</b>  |                 | <b>DRUG FACTS:</b> (continued)  |  |
| <b>ACTIVE INGREDIENT:</b><br>Sodium Fluoride - 0.243% (0.15% w/v fluoride ion) .....Anticavity  | <b>PURPOSE:</b> | <b>DIRECTIONS:</b> <b>Adults and children 2 years &amp; older:</b> Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. • Do not swallow. • Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing, use a pea-sized amount) • Supervise children's brushing until good habits are established. • <b>Children under 2 years:</b> Consult a dentist or doctor. |  |
| <b>USES:</b> Aids in the prevention of dental cavities.   |                 | <b>INACTIVE INGREDIENTS:</b> Sorbitol, Silica, Treated Water, Glycerin, PEG-32, Sodium Lauryl Sulfate, Flavor, Titanium Dioxide, Cellulose Gum, Carrageenan, Trisodium Phosphate, Sodium Saccharin, Sodium Benzoate, Tetrasodium Pyrophosphate, FD&C Blue # 1.  |  |
| <b>WARNINGS:</b><br>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. |                 |   |  |



Product of India  
Distributed By: NWI, Inc., 160 Athens Way, Nashville, TN 37228

## FRESHMINT PREMIUM ANTICAVITY

sodium fluoride paste, dentifrice

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:51824-029 |
| <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) | SODIUM FLUORIDE   | 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>GLYCERIN</b> (UNII: PDC6A3C0OX)                                   |          |
| <b>POLYETHYLENE GLYCOL 1600</b> (UNII: 1212Z7S33A)                   |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                      |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                           |          |
| <b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311) |          |
| <b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)                                |          |

|   |  |
|---|--|
| <b>SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE</b> (UNII: B70850QPHR) |  |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                           |  |
| <b>SODIUM SACCHARIN</b> (UNII: SB8ZUX40TY)                          |  |
| <b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)                      |  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                       |  |

### Product Characteristics

|                 |                 |                     |  |
|-----------------|-----------------|---------------------|--|
| <b>Color</b>    | blue (sky blue) | <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:51824-029-02 | 144 in 1 CARTON                                   | 01/01/2013           |                    |
| 1 | NDC:51824-029-01 | 24 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:51824-029-05 | 144 in 1 CARTON                                   | 01/01/2013           |                    |
| 2 | NDC:51824-029-04 | 36 in 1 BOX                                       |                      |                    |
| 2 | NDC:51824-029-03 | 43 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| 3 | NDC:51824-029-07 | 72 in 1 CARTON                                    | 01/01/2013           |                    |
| 3 | NDC:51824-029-06 | 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                                     | 01/01/2013           |                    |

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

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