

**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**

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 (aqua), Glycerin, Polyethulene Glycol 1500, Sodium Lauryl Sulphate, Flavor, Titanium Dioxide, Cellulose Gum, Carrageenan, Trisodium Orthophosphate, Sodium Saccharin, Sodium Benzoate, Tetrasodium Pyrophosphate, Methylparaben, Propylparaben, Color: FD&C Blue #1



B: No xxxxx

Exp: Mmmmyyy

**ADA Accepted** The ADA's Council on Scientific Affairs' Acceptance of Freshmint Premium Anticavity Toothpaste is based on its finding that the product is effective in helping to prevent or reduce tooth decay when used as directed. — Council on Scientific Affairs, American Dental Association.

|  |                               |                                      |   |
|--|-------------------------------|--------------------------------------|---|
| <b>DRUG FACTS:</b>   |                               | <b>DIRECTIONS:</b>                   |   |
| <b>ACTIVE INGREDIENT:</b><br>Sodium Fluoride — 0.243% (0.15 w/v fluoride ion)...   | <b>PURPOSE:</b><br>Anticavity | Adults and children 2 years & older: | <ul style="list-style-type: none"> <li>Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist.</li> <li>Do not swallow.</li> <li>To minimize swallowing use a pea-sized amount in children under 6 years of age.</li> <li>Supervise children's brushing until good habits are established.</li> </ul> |
| <b>USES:</b> Helps protect teeth and roots against cavities.   |                               | Children under 2 years:              | <ul style="list-style-type: none"> <li>Ask a dentist.</li> </ul>  |
| <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>INACTIVE INGREDIENTS:</b> Sorbitol, Silica, Treated Water (Aqua), Glycerin, Polyethylene Glycol 1500, Sodium Lauryl Sulphate, Flavor, Titanium Dioxide, Cellulose Gum, Carrageenan, Trisodium Orthophosphate, Sodium Saccharin, Sodium Benzoate, Tetrasodium Pyrophosphate, Methylparaben, Propylparaben. Color: FD & C Blue # 1. |                               |                                      |   |



Product of India, Exclusive Distributor: NWI, Inc., 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:Q80VPU4080) | 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 1500</b> (UNII: 1212Z7S33A)                  |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                     |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                          |          |
| <b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)             |          |
| <b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)                               |          |
| <b>SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE</b> (UNII: B70850QPHR) |          |
| <b>Sodium benzoate</b> (UNII: OJ245FE5EU)                           |          |
| <b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)                      |          |

|   |  |
|---|--|
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)       |  |
| <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 (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)

Revised: 11/2023

New World Imports, Inc