

FRESHMINT PREMIUM ANTICAVITY- 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 (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. MMM/YYYY



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.

DRUG FACTS:		DIRECTIONS:	
ACTIVE INGREDIENT: Sodium Fluoride – 0.243% (0.15% w/v fluoride ion)	PURPOSE: Anticavity	Adults and children 2 years & older:	<ul style="list-style-type: none"> 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.
USES: Helps protect teeth and roots against cavities.		Children under 2 years:	<ul style="list-style-type: none"> Ask a dentist.
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.			
INACTIVE INGREDIENTS: 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-034
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.43 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
CARRAGEENAN (UNII: 5C69YCD2YJ)
SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR)
POTASSIUM SODIUM SACCHARATE DIHYDATE (UNII: 6SI0K9D9KF)
Sodium benzoate (UNII: OJ245FE5EU)
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Product Characteristics

Color	blue (sky blue)	Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-034-01	130 g in 1 TUBE; Type 0: Not a Combination Product	04/04/2013	
2	NDC:51824-034-09	8 g in 1 PACKET; Type 0: Not a Combination Product	09/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	04/04/2013	

Labeler - New World Imports, Inc (075372276)

Registrant - New World Imports, Inc (075372276)