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

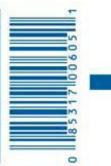
Inactive Ingredients

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



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: PURPOSE: Sodium Fluoride - 0.243% (0.15% w/v fluoride ion)	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.	
USES: Helps protect feeth and roots against cavities.		 To minimize swallowing use a pea-sized amount in children under 6 years of age. 	
WARNINGS: Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek		Supervise children's brushing until good habits are established.	
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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:Q80VPU4080) FLUORIDE ION 2.43 mg in 1 g

Inactive Ingredients

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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: K6790BS311)	
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
NDC:51824-034-	130 g in 1 TUBE; Type 0: Not a Combination Product	04/04/2013	
NDC:51824-034- 09	8 g in 1 PACKET; Type 0: Not a Combination Product	09/01/2016	

Marketing In	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)

Revised: 11/2023 New World Imports, Inc