

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

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. 4.6 OZ (130g)

DRUG FACTS:		DRUG FACTS: (continued)	
ACTIVE INGREDIENT: Sodium Fluoride - 0.243% (0.15% w/v fluoride ion)	PURPOSE: Anticavity	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.	
USES: Aids in the prevention of dental cavities.		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.	
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.			



• Helps prevent cavities



Product of India

Distributed By: NWI, Inc., 160 Athens Way, 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

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR)	
SODIUM SACCHARIN (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
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)