

FRESHMINT ANTICAVITY FLUORIDE- sodium fluoride gel, dentifrice
New World Imports, Inc

Drug Facts

Sodium Fluoride - 0.22% (0.1% w/v fluoride ion)

Anticavity

Keep out of reach of children 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Helps protect against cavities

Keep out of reach of children.

Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.

Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).

Children under 2 years: Ask a dentist or physician

Treated Water, Sorbitol, Carbopol, Sodium Lauryl Sulphate, Flavor, Polyethylene Glycol 1500, Sodium Saccharin, Precipitated Silica, Sodium Carboxy Methyl Cellulose, Methylparaben, Propylparaben.

freshmint®

ANTICAVITY FLUORIDE GEL TOOTHPASTE

NET WT. 6.4 OZ
(181 GRAMS)

DRUG FACTS:			
ACTIVE INGREDIENT: Sodium fluoride - 0.22% (0.1% w/v fluoride ion)	PURPOSE: Anticavity.	DIRECTIONS: Adults & Children 6 years of age & older:	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
USE: Helps protect against cavities.		Children 2 to 6 years:	Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
WARNINGS: Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.		Children under 2 years:	Ask a dentist or physician.
	INACTIVE INGREDIENTS: Treated Water, Sorbitol, Carbopol, Sodium Lauryl Sulfate, Flavor, Poly Ethylene Glycol 1500, Sodium Saccharin, Precipitated Silica, Sodium Carboxy Methyl Cellulose, Methylparaben, Propylparaben.		

Product of India, Exclusive Distributor: NWI, Inc., Nashville, TN 37228.



FRESHMINT ANTICAVITY FLUORIDE

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-068
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU4080)	Fluoride Ion	2.2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Sorbitol (UNII: 506T60A25R)
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)
Sodium Lauryl Sulfate (UNII: 368GB5141J)
Polyethylene Glycol 1500 (UNII: 1212Z7S33A)
Saccharin Sodium (UNII: SB8ZUX40TY)
Silicon Dioxide (UNII: ETJ7Z6XBU4)
Carboxymethylcellulose Sodium (UNII: K679OBS311)
Methylparaben (UNII: A2I8C7HI9T)
Propylparaben (UNII: Z8IX2SC1OH)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-068-01	7.9 g in 1 PACKET; Type 0: Not a Combination Product	09/17/2010	
2	NDC:51824-068-02	17 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
3	NDC:51824-068-03	24 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
4	NDC:51824-068-04	43 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
5	NDC:51824-068-05	78 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
6	NDC:51824-068-06	130 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
7	NDC:51824-068-07	181 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	09/17/2010	

Labeler - New World Imports, Inc (075372276)