

**FRESHMINT ANTICAVITY FLUORIDE- sodium monofluorophosphate paste,
dentifrice**

New World Imports, Inc

Drug Facts

Sodium Monofluorophosphate - .76%

(Total Fluoride Content - 1000 ppm Approx.)

Anticavity

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 immediately.

Helps protect against cavities

Keep out of reach of children under 6 years of age.

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.

Calcium Carbonate, Treated Water, Sorbitol, Precipitated Silica, Sodium Lauryl Sulphate, Flavor, Sodium Carboxy Methyl Cellulose, Sodium Silicate, Tetra Sodium Pyrophosphate, Sodium Saccharin, Methylparaben, Titanium Dioxide, Polyethylene Glycol 400, Propylparaben

freshmint[®]

ANTICAVITY FLUORIDE TOOTHPASTE

NET WT 6.4 OZ
(181 GRAMS)

DRUG FACTS:			
ACTIVE INGREDIENT: Sodium Monofluorophosphate - 0.76% (Total Fluoride Content - 1000 ppm Approx.)	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 immediately.		Children under 2 years:	Ask a dentist or physician.
	INACTIVE INGREDIENTS: Calcium Carbonate, Treated Water, Sorbitol, Precipitated Silica, Sodium Lauryl Sulfate, Flavor, Sodium Carboxy Methyl Cellulose, Sodium Silicate, Tetra Sodium Pyrophosphate, Sodium Saccharin, Methylparaben, Titanium Dioxide, Poly Ethylene Glycol 400, Propylparaben.		

Exp. Date & Batch No. on crimp.

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

FRESHMINT ANTICAVITY FLUORIDE

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-067
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU4080)	Fluoride Ion	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength

Calcium Carbonate (UNII: H0G9379FGK)
Water (UNII: 059QF0K00R)
Sorbitol (UNII: 506T60A25R)
Silicon Dioxide (UNII: ETJ7Z6XBU4)
Sodium Lauryl Sulfate (UNII: 368GB5141J)
Carboxymethylcellulose Sodium (UNII: K679OBS311)
Sodium Silicate (UNII: IJF18F77L3)
Sodium phosphate, tribasic, dodecahydrate (UNII: B70850QPHR)
Saccharin Sodium (UNII: SB8ZUX40TY)
Methylparaben (UNII: A2I8C7HI9T)
Titanium Dioxide (UNII: 15FIX9V2JP)
Polyethylene Glycol 400 (UNII: B697894SGQ)
Propylparaben (UNII: Z8IX2SC1OH)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-067-01	17 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	
2	NDC:51824-067-02	17 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	
3	NDC:51824-067-03	24 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	
4	NDC:51824-067-04	43 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	
5	NDC:51824-067-05	43 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	
6	NDC:51824-067-06	78 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	
7	NDC:51824-067-07	78 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	
8	NDC:51824-067-08	130 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	
9	NDC:51824-067-09	181 g in 1 TUBE; Type 0: Not a Combination Product	09/16/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	09/16/2010	

