

**SAFETYMAXX MINT FLAVOR - sodium monofluorophosphate paste, dentifrice
FSi, Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SafetyMAXX Mint Flavor

Active Ingredient

Sodium Monofluorophosphate - 0.76% (Total fluoride content - 1000ppm Approx)

Purpose

Anticavity

Use:

Helps protect against cavities

Warnings

If more than used for brushing is swallowed, get medical help or contact a Poison Control Center immediately.

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

Directions

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.

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

Inactive Ingredients

Calcium carbonate, Purified 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 Propyl Paraben

Product of China, Exclusively produced for FSi, Inc. 1-800-647-5923 www.myfsi.net Expires 2 years from the Date of Mfg

FSi, Inc Nashville TN 37210

Product Tube Label



**Mint
Flavor**

NET WT. 4.6 OZ
(130 GRAMS)

Mfg. Date & Batch No. on crimp.

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, Purified Water, Sorbitol, Precipitated Silica, Sodium Lauryl Sulphate, Flavor, Sodium Carboxy Methyl, Cellulose, Sodium Silicate, Tetra Sodium Pyrophosphate, Sodium Saccharin, Methyl Paraben, Titanium Dioxide, Poly Ethylene Glycol400, Propyl Paraben.	

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SAFETYMAXX MINT FLAVOR

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60371-339
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYL PARABEN (UNII: Z8IX2SC10H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60371-339-06	17 g in 1 TUBE		
2	NDC:60371-339-85	24 g in 1 TUBE		
3	NDC:60371-339-15	43 g in 1 TUBE		
4	NDC:60371-339-27	78 g in 1 TUBE		
5	NDC:60371-339-46	130 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/15/2011	

Labeler - FSi, Inc. (609296694)

Revised: 11/2011

FSi, Inc.