

**SAFETYMAXX MINT FLAVOR - sodium fluoride gel, 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 Fluoride - 0.22% (0.1%w/v fluoride ion)

**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**

Purified water, Sorbitol, Carbopol, Sodium Lauryl Sulphate, Flavor, Poly Ethylene Glycol 1500, Sodium Saccharin, Precipitated Silica, Sodium Carboxy Methyl Cellulose, Methyl Paraben, Propyl Paraben

Product of China, Exclusively produced for FSi, Inc. 1-800-647-5923 [www.myfsi.net](http://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)

DRUG FACTS		
ACTIVE INGREDIENT: PURPOSE Sodium fluoride - 0.22% (0.1% w/v fluoride ion) .... 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: Purified Water, Sorbitol, Carbopol, Sodium Lauryl Sulphate, Flavor, Poly Ethylene Glycol 1500, Sodium Saccharin, Precipitated Silica, Sodium Carboxy Methyl Cellulose, Methyl Paraben, Propyl Paraben.	

Mfg. Date & Batch No. on crimp.

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

## SAFETYMAXX MINT FLAVOR

sodium fluoride gel, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60371-344
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.22 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60371-344-06	17 g in 1 TUBE		

2	NDC:60371-344-85	24 g in 1 TUBE		
3	NDC:60371-344-15	43 g in 1 TUBE		
4	NDC:60371-344-46	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.