# SMILE DIRECT CLUB- sodium fluoride toothpaste paste, dentifrice Nutrix, LLC

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.

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#### **Active Ingredient**

Sodium Fluoride 0.24%

#### Purpose

Anticavity.

#### **Indications and Usage Section**

Aids in the prevention of dental cavities.

#### Warnings

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

#### Keep out of Reach of Children

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

#### Directions

- **Adults and children 2 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 doctor.

- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age. Consult a dentist or doctor.

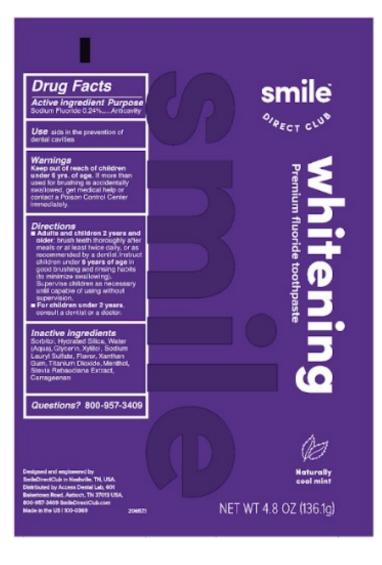
#### **Inactive Ingredients**

Sorbitol, Hydrated Silica, Water (Agua), Glycerin, Xylitol, Sodium Lauryl Sulfate, Flavor, Xanthan Gum, Titanium Dioxide, Menthol, Stevia Rebaudiana Extract, Carrageenan.

#### Questions?

800-957-3409

#### Principle package label



**Primary Packaging - Carton** 



SMILE DIRECT CLUB sodium fluoride toothpaste paste, dentifrice								
Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Sourc	Item Code (Source)		NDC:73333-125			
Route of Administration	ORAL							
Active Ingredient/Active M	Ioiety							
	rength	Strength						
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION					2.4 mg in 1 g			
Inactive Ingredients								
Ingredient Name					Strength			
GLYCERIN (UNII: PDC6A3C0OX)								
HYDRATED SILICA (UNII: Y6O7T4	G8P9)							
WATER (UNII: 059QF0KO0R)								

XYLITOL (UNII: VCQ006KQ1E)								
S	O DIUM LAURYL SU	LFATI	: (UNII: 368GB5141J)					
MINT (UNII: FV98Z8GITP)								
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)								
XANTHAN GUM (UNII: TTV12P4NEE)								
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)								
CARRAGEENAN (UNII: 5C69 YCD2YJ)								
SORBITOL (UNII: 506T60A25R)								
Μ	MENTHOL (UNII: L7T10EIP3A)							
Product Characteristics								
Color			white	Score				
Shape				Size				
Flavor				Imprint Code				
F	lavor		MINT (Cool Mint)	Imprint Code				
	lavor ontains		MINT (Cool Mint)	Imprint Code				
			MINT (Cool Mint)	Imprint Code				
			MINT (Cool Mint)	Imprint Code				
С			MINT (Cool Mint)	Imprint Code				
С	ontains		MINT (Cool Mint) Package Description	Imprint Code Marketing Start Date	Marketing End Date			
C P #	ontains ackaging	1 in 1 (	Package Description		Marketing End Date			
C P #	ontains ackaging Item Code		Package Description	Marketing Start Date	Marketing End Date			
C P # 1	ontains ackaging Item Code		Package Description	Marketing Start Date	Marketing End Date			
C P # 1	ontains ackaging Item Code		Package Description	Marketing Start Date	Marketing End Date			
C P # 1	ontains ackaging Item Code NDC:73333-125-01	125 g i	<b>Package Description</b> CARTON n 1 TUBE; Type 0: Not a Combination Product	Marketing Start Date	Marketing End Date			
C # 1 1	ontains ackaging Item Code NDC:73333-125-01	125 g i	Package Description CARTON n 1 TUBE; Type 0: Not a Combination Product	Marketing Start Date 09/25/2019				
C # 1 1	ontains ackaging Item Code NDC:73333-125-01 Marketing Inf	125 g i Orma y A	Package Description CARTON a 1 TUBE; Type 0: Not a Combination Product Ation Oplication Number or Monograph Citation	Marketing Start Date 09/25/2019 Marketing Start Date	Marketing End Date Marketing End Date			
C P 1 1 N N	ontains ackaging Item Code NDC:73333-125-01	125 g i	Package Description CARTON a 1 TUBE; Type 0: Not a Combination Product Ation Oplication Number or Monograph Citation	Marketing Start Date 09/25/2019				

## Labeler - Nutrix, LLC (079833114)

### Establishment

Name	Address	ID/FEI	Business Operations
Nutrix,LLC		079833114	manufacture(73333-125)

Revised: 9/2019

Nutrix, LLC