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

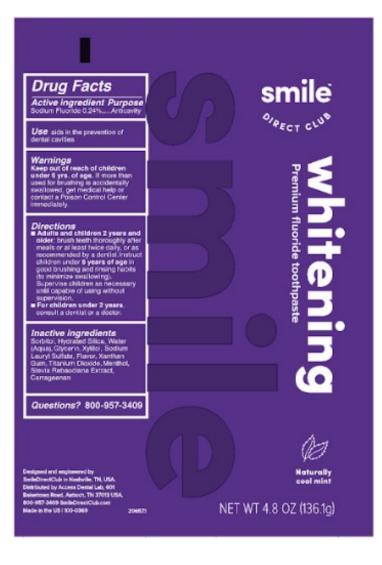
## **Inactive Ingredients**

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 CLU sodium fluoride toothpaste pa						
Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Sou	Item Code (Source)		NDC:73333-125	
Route of Administration	ORAL					
Active Ingredient/Active			Dania of Stu	angth	Stron - th	
Ingredient NameBasis of StreetSODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)FLUORIDE ION					Strengtl 2.4 mg in 1	
Inactive Ingredients						
Ingredient Name					Strength	
HYDRATED SILICA (UNII: Y607	Γ4G8P9)					
WATER (UNII: 059QF0KO0R)						
<b>XYLITOL</b> (UNII: VCQ006KQ1E)						

SODIUM LAURYL SUL	FATE (UNII: 368GB5141J)						
MINT (UNII: FV98Z8GITP)							
TITANIUM DIO XIDE (U	TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)						
XANTHAN GUM (UNII: TTV12P4NEE)							
STEVIA REBAUDIUNA	LEAF (UNII: 6TC6NN0876)						
CARRAGEENAN (UNII: 5C69YCD2YJ)							
SORBITOL (UNII: 506T60A25R)							
MENTHOL (UNII: L7T10	)EIP3A)						
GLYCERIN (UNII: PDC6	A3C0OX)						
Product Characteristics							
Color	white	Score					
Shape		Size					
Flavor	MINT (Cool Mint)	Imprint Code					
Contains							
Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
<b>1</b> NDC:73333-125-03	1 in 1 CARTON	09/25/2019					
1 1	125 g in 1 TUBE; Type 0: Not a Combination Product						
Marketing Information							
Marketing Category		Marketing Start Date	Marketing End Date				
OTC monograph final	part355	09/25/2019	J				
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# Labeler - Nutrix International, LLC (117341868)

Establishment							
Name	Address	ID/FEI	Business Operations				
Nutrix International,LLC		117341868	manufacture(73333-125)				

Revised: 1/2020

Nutrix International, LLC