

**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 immediately.

**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**

**Drug Facts**

**Active Ingredient Purpose**  
Sodium Fluoride 0.24%.....Aids cavity

**Use** aids in the prevention of dental cavities

**Warnings**  
Keep out of reach of children under 6 yrs. of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

**Directions**  

- Adults and children 2 years and older: brush teeth thoroughly after meals or at least twice daily, or as recommended by a dentist. 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.
- For children under 2 years, consult a dentist or a doctor.

**Inactive ingredients**  
Sorbitol, Hydrated Silica, Water (Aqua), Glycerin, Xylitol, Sodium Lauryl Sulfate, Flavor, Xanthan Gum, Titanium Dioxide, Menthol, Stevia Rebaudiana Extract, Carrageenan

**Questions? 800-957-3409**



**Whitening**  
Premium fluoride toothpaste



NET WT 4.8 OZ (136.1g)

Designed and engineered by SmileDirectClub in Knoxville, TN, USA.  
 Distributed by Access Dental Lab, 601 Bakersown Road, Aetech, TN 37013 USA.  
 800-957-3409 SmileDirectClub.com  
 Made in the US | 100-0369 209571

**Primary Packaging - Carton**



## SMILE DIRECT CLUB

sodium fluoride toothpaste paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73333-125
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.4 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0K00R)	
XYLITOL (UNII: VCQ006KQ1E)	

<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>MINT</b> (UNII: FV98Z8G1TP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>STEVIA REBAUDIUNA LEAF</b> (UNII: 6TC6NN0876)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MENTHOL</b> (UNII: L7T10EP3A)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Cool Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73333-125-03	1 in 1 CARTON	09/25/2019	
1		125 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/25/2019	

**Labeler** - Nutrix International, LLC (117341868)

**Establishment**

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