

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.

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



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
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	

XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MINT (UNII: FV98Z8GITP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SORBITOL (UNII: 506T60A25R)	
MENTHOL (UNII: L7T10EIP3A)	

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
1	NDC:73333-125-01	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, LLC (079833114)

Establishment

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

Revised: 9/2019

Nutrix, LLC