

SMILE DIRECT CLUB- sensitivity 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.

Active Ingredient

Sodium Fluoride 0.24%

Purpose

Anticavity

Indications

Aids in the prevention of dental decay.

Warnings

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

Keep out of reach

Keep out of reach of children under 6 years 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, Stevia Rebaudiana Extract, Aloe Barbadensis Leaf Extract, Cocamidopropyl Betaine, Menthol.

Questions

800-957-3409

Primary Packaging Label

Drug Facts

Active ingredients Purpose

Potassium Nitrate 5%...Antisensitivity
Sodium Fluoride 0.24%.....Anticavity

Uses ■ aids in the prevention of dental cavities ■ builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact

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. When using this product, do not use for sensitivity for longer than 4 weeks unless recommended by a dentist.

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, Cocos nucifera (Coconut) Oil, Sodium Lauryl Sulfate, Flavor, Xanthan Gum, Titanium Dioxide, Stevia Rebaudiana Extract, Aloe Barbadensis Leaf Extract, Cocamidopropyl Betaine, Menthol

Questions? 800-957-3409

Designed and engineered by
SmileDirectClub in Nashville, TN, USA.
Distributed by Access Dental Lab, 601
Bekertown Road, Antioch, TN 37013 USA,
800-957-3409 SmileDirectClub.com
Made in the US | 100-0370

20658.1

smile[™]
DIRECT CLUB

Premium fluoride toothpaste
sensitivity



Soothing
cool mint

NET WT 4.4 OZ (124.7g)



SMILE DIRECT CLUB

sensitivity toothpaste paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73333-126
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	
XYLITOL (UNII: VCQ006KQ1E)	
STEVIA REBAUDIANA WHOLE (UNII: 6U422Y08O2)	
MENTHOL (UNII: L7T10EIP3A)	
MINT (UNII: FV98Z8G1TP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCONUT OIL (UNII: Q9L0O73W7L)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73333-126-02	1 in 1 CARTON	11/22/2019	
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	11/22/2019	

Labeler - Nutrix International, LLC (117341868)

Establishment

Name	Address	ID/FEI	Business Operations
Nutrix, LLC		079833114	manufacture(73333-126)