

SMILE DIRECT CLUB- sensitivity 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

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

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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:73333-126-01 | 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, LLC (079833114)

Establishment

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