**DENTAL PLUS WHITENING- sodium monofluorophosphate paste**
**tropical degil cosmetics industries ltd**

*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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**Dental Plus Whitening**

## Active Ingredient

Sodium monofluorophosphate 0.8% (1,000 ppm F)

## Purpose

anticavity

## Use

Aids in the prevention of dental cavities

## Ask a dentist before use if you have

bleeding or redness lasting more than 2 weeks, pain, swelling, pus, loose teeth, or more spacing between teeth. These may be signs of periodontitis, a serious form of gum disease.

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

## Directions

- **Adults and children 2 years of age and older:** Brush teeth thoroughly, preferrably 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

water, sorbitol, calcium carbonate, silica, PEG-32, sodium lauryl sulphate, flavor, cellulose gum, sodium bicarbonate, flavor, titanium dioxide, sodium saccharin, sodium benzoate, benzoic acid, zinc citrate

Questions or comments? www.sleeksensation.com

Dental Plus Whitening

Anticavity Fluoride Toothpaste

Net Wt 5.1 oz (145 g)


# DENTAL PLUS WHITENING

sodium monofluorophosphate paste

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:62685-216 |
| **Route of Administration** | DENTAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **SODIUM MONOFLUOROPHOSPHATE** (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 1 mg in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CALCIUM CARBONATE** (UNII: H0G9379FGK) | |
| **POLYETHYLENE GLYCOL 1600** (UNII: 1212Z7S33A) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **BENZOIC ACID** (UNII: 8SKN0B0MIM) | |
| **ZINC CITRATE** (UNII: K72I3DEX9B) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **CARBOXYMETHYLCELLULOSE SODIUM** (UNII: K679OBS311) | |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:62685-216-03 | 1 in 1 BOX | 02/01/2021 | |
| **1** | | 145 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 | 02/01/2021 | |

## Labeler - tropical degil cosmetics industries ltd (600437230)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| tropical degil cosmetics industries ltd | | 600437230 | manufacture(62685-216) |

Revised: 2/2021 tropical degil cosmetics industries ltd