

## **DENTAL PLUS FRESH MINT FLAVOR- 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 Fresh Mint Flavor**

#### **Active ingredient**

Sodium monofluorophosphate 0.8% (1000 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, 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.

Water, sorbitol, calcium carbonate, silica, sodium lauryl sulphate, flavor, cellulose gum, sodium saccharin, sodium benzoate, benzoic acid.

Questions or comments? [www.sleeksensation.com](http://www.sleeksensation.com)

#### **Principial Display Panel**

Dental plus fresh mint flavor

anticavity fluoride toothpaste

Net Wt 5.1 oz - 145 g



## DENTAL PLUS FRESH MINT FLAVOR

sodium monofluorophosphate paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62685-218
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62685-218-	1.5 1.5 OZ	02/01/2021	

1	03	1 III I BOX	02/01/2021	
1		145 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355		02/01/2021	

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

<b>Establishment</b>				
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>	
tropical degil cosmetics industries ltd		600437230	manufacture(62685-218)	

Revised: 2/2021

tropical degil cosmetics industries ltd