

## **DENTAL PLUS EXTRA MINT- 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 Extra Menta**

#### **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, 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.

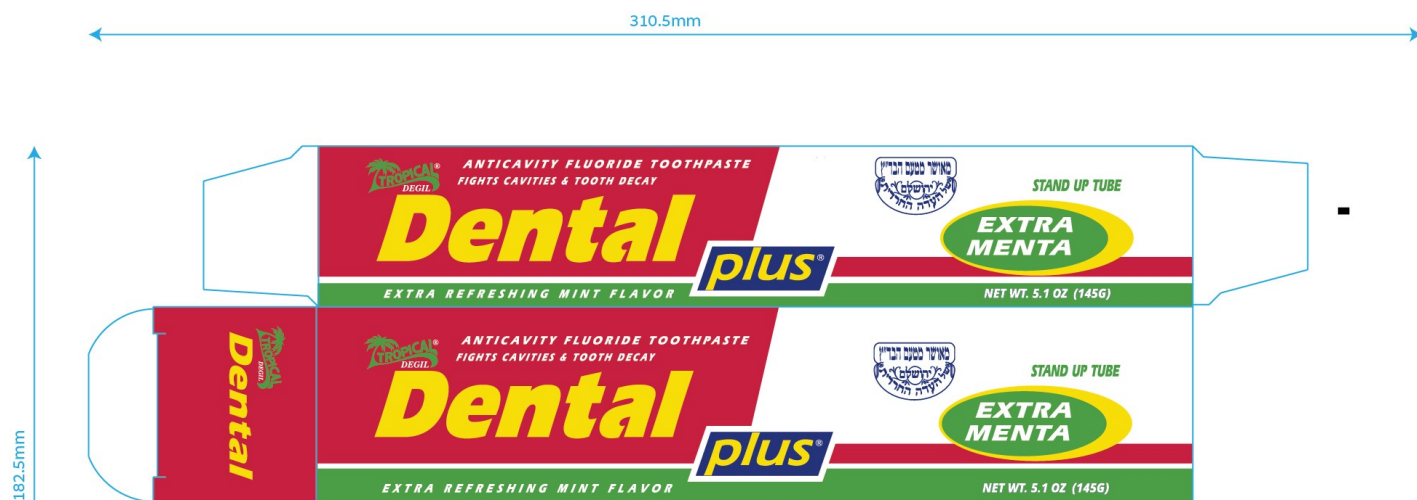
#### **Inactive ingredients**

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)

#### **Principal Display Panel**

Dental Plus Extra Menta  
 Anticavity Fluoride Toothpaste  
 Net Wt 5.1 oz (145 g)



## DENTAL PLUS EXTRA MINT

sodium monofluorophosphate paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62685-206
<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:Q80VPU408O)	FLUORIDE ION	1 mg in 1 g

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62685-206-03	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(62685-206)

Revised: 2/2021

tropical degil cosmetics industries ltd