

DENTAL PLUS REGULAR 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.

Dental Plus Regular Flavor

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

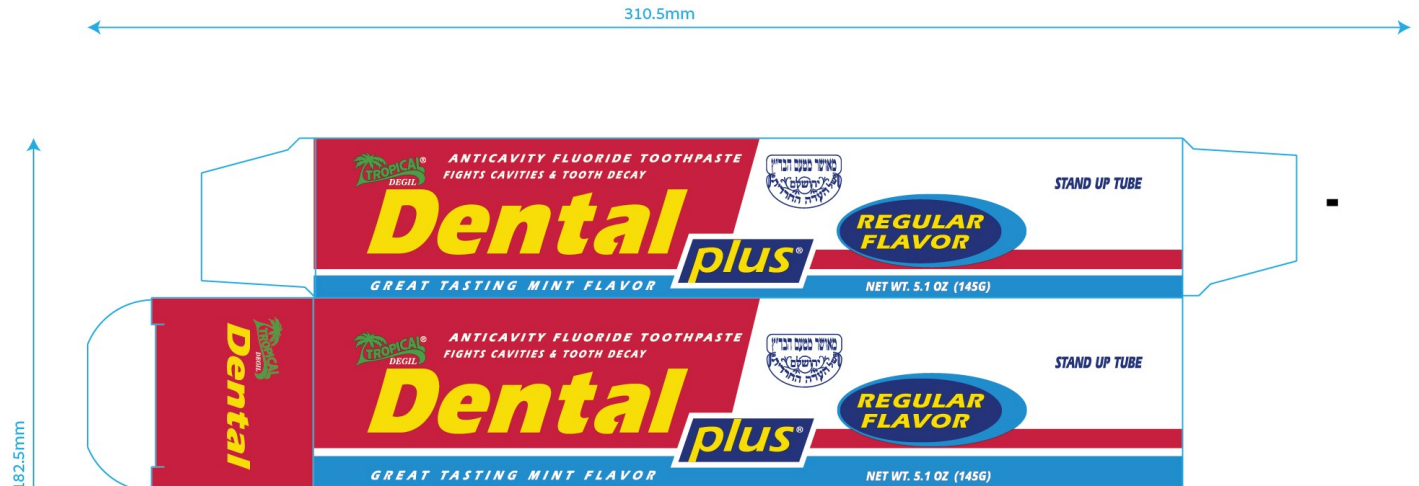
Water, sorbitol, calcium carbonate, silica, sodium lauryl sulphate, flavor, cellulose gum, sodium saccharin, sodium benzoate, benzoic acid.

Questions or comments? www.sleeksensation.com

Dental Plus Regular Flavor

Anticavty Fluoride Toothpaste

Net Wt 5.1 oz (145 g)



DENTAL PLUS REGULAR FLAVOR

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62685-217
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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:62685-217			

1	NDC:62685-217-03	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(62685-217)

Revised: 2/2021

tropical degil cosmetics industries ltd