

DENTAL PLUS REGULAR FLAVOR - sodium monofluorophosphate paste, dentifrice
Tropical International Manufacturing Inc

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.

Drug facts

Active Ingredient

Sodium Monofluorophosphate 0.8% (1000 ppm F)

Purpose

anticavity

Use

For cavity prevention and tooth protection.

Warnings

Keep out of the 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.

Drug Facts (continued)

Dental plus Regular Flavor 200 g

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 dentist or physician.
Children 2 to 6 years	Use only a pea-sized amount and supervise child brushing and rinsing (to minimize swallowing)
Children under 2 years	Ask a dentist or a physician

Inactive ingredients

Water, Sorbitol, Calcium Carbonate, Silica, Sodium Lauryl Sulphate, Flavor, Cellulose Gum, Sodium saccharin, Sodium Benzoate.

Questions? Comments?

call toll-free 1-888-777-8767. Monday-Friday 9am-5pm

Made by Tropical Degil Cosmetics

Ind. Ltd. Kiryat Shmona, Israel for
 Tropical International Cosmetics, Inc.
 18 Stewart Street,
 Brooklyn, NY 11207 USA
 Made in Israel

PRINCIPAL DISPLAY PANEL - 7 oz Tube
 ANTICAVITY FLUORIDE TOOTHPASTE
 FIGHTS CAVITIES and TOOTH DECAY
Tropical DEGIL Dental plus REGULAR FLAVOR
 NEW GIANT SIZE STAND UP TUBE
 GREAT TASTING MINT FLAVOR
 NET WT. 7 OZ (200 G)



 Made by Tropical Degil Cosmetics Ind. Ltd. Kiryat Shmona, Israel for Tropical International Cosmetics, Inc. 18 Stewart Street, Brooklyn, NY 11207 USA Made in Israel 	Drug Facts Active ingredient Purpose Sodium Monofluorophosphate 0.8% (1,000 ppmF)..... anticavity Use: For cavity prevention & Tooth Protection.	Drug Facts (continued) Dental plus Regular Flavor 200g 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 dentist or physician. Children 2 to 6 years Use only a pea-sized amount and supervise child brushing and rinsing (to minimize swallowing) Children under 2 years Ask a dentist or a physician	
	Warnings: Keep out of the 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.	Inactive ingredients: Water, Sorbitol, Calcium Carbonate, Silica, Sodium Lauryl Sulphate, Flavor, Cellulose Gum, Sodium saccharin, Sodium Benzoate.	
		Questions? Comments? call toll-free 1-888-777-8767. Monday-Friday 9am-5pm	

DENTAL PLUS REGULAR FLAVOR

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62678-217
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)		SODIUM MONOFLUOROPHOSPHATE	8 mg in 1 g	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62678-217-17	1 in 1 CARTON		
1		200 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	05/19/2010		

Labeler - Tropical International Manufacturing Inc (962685884)

Establishment

Name	Address	ID/FEI	Business Operations
Tropical Degil Cosmetics Industries LTD		600437230	manufacture, label, pack, analysis

Revised: 5/2010

Tropical International Manufacturing Inc