

DENTAL PLUS WHITENING - 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% (1,000 ppmF)

Purpose

anticavity

Use

For cavity prevention, Tooth Protection and Whiter Teeth.

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 Whitening 172g

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, PEG-32, Sodium Lauryl Sulphate, Cellulose Gum, Sodium Bicarbonate, Flavor, Titanium Dioxide, Sodium Saccharin, Sodium Benzoate, Zinc Citrate

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 - 6 oz Tube
 ANTICAVITY FLUORIDE TOOTHPASTE
Tropical DEGIL Dental plus Whitening
 FOR HEALTHY AND BRIGHT TEETH
 NET WT.6 OZ (172 G) Cont. Neto: 6 oz (172 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	Drug Facts (continued) Dental plus Whitening 172g		For best results, squeeze tube from the bottom and flatten as you go up
	Active ingredient Purpose Sodium Monofluorophosphate 0.8% (1,000 ppmF)..... anticavity	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.		
	Use: For cavity prevention, Tooth Protection & Whiter Teeth.	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	
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DENTAL PLUS WHITENING			
sodium monofluorophosphate paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62678-216
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:62678-216-16	1 in 1 CARTON		
1		172 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