DENTAL PLUS BAKING SODA - 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 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 Baking Soda 200 g

Directions

Adults and children 2 Brush teeth thoroughly, preferably after each meal or at years of age and older 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, Sodium Bicarbonate, Flavor, Cellulose Gum, 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 - 7 oz Tube

ANTICAVITY FLUORIDE TOOTHPASTE FIGHTS CAVITIES and TOOTH DECAY Tropical DEGIL Dental plus BAKING SODA NEW GIANT SIZE STAND UP TUBE WITH BAKING SODA AND CALCIUM NET WT. 7 OZ (200 G)



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35 Made	_	Made by Tropics Ind. Ltd. Kiryat 9 Tropical Internati 18 Stewart Street Brooklyn, NY 112	Active ingredientPurpose Sodium Monofluorphosphate 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.
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2	7	Inc.		Questions? Comment	s? call toll-free 1-888-777-8767. Monday-Friday 9am-5pm

DENTAL PLUS BAKING SODA sodium monofluorophosphate paste, dentifrice Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:62678-207 Route of Administration DENTAL Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	SODIUM MONOFLUOROPHOSPHATE	8 mg in 1 g

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:62678-207-07	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