NATURE MINT ANTICAVITY- sodium monofluorophosphate paste, dentifrice Bob Barker Company 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.

Nature Mint_® **Anticavity**

Drug Facts:

Active ingredient

Sodium Monofluorophosphate - 0.76% (0.1% w/v fluoride ion)

Purpose

Anticavity toothpaste

Use

Helps protect against cavities.

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 immediately.

Directions

Adults & Children	Brush teeth thoroughly, preferably after each
6 years of age &	meal or at least twice a day, or as directed by a
older:	dentist or doctor.
Children 2 to 6 years:	Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
Children under 2 years:	Ask a dentist or physician.

Inactive Ingredients

Calcium Carbonate, Water, Sorbitol, Glycerin, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Sodium Saccharin, Tetrasodium Pyrophosphate, Sodium Benzoate

Dist. by Bob Barker Co. Inc. Fuquay-Varina, NC 27526

PRINCIPAL DISPLAY PANEL - 24 GRAM Tube Label

Nature Mint_®

ANTICAVITY FLUORIDE TOOTHPASTE SODIUM MONOFLUOROPHOSPHATE - 0.76% FRESH MINT FLAVOR



Drug Facts:	Drug Facts (continued)	
Active ingredient: Purpose: Sodium Monofluorophosphate - 0.76% (0.1% w/v fluoride ion)Anticavity toothpaste	Directions: Adults & Children 6 years of age & older:	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
Use: Helps protect against cavities.	Children 2 to 6 years:	Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
Warnings:	Children under 2 years:	Ask a dentist or physician.
Keep out of the reach of children uncler 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.	Inactive Ingredients: Calcium Carbonate, Water, Sorbitol, Glycerin, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Sodium Saccharin, Tetrasodium Pyrophosphate, Sodium Benzoate	

NATURE MINT ANTICAVITY

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53247-123
Route of Administration	DENTAL		

l	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
	Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	7.6 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
Calcium Carbonate (UNII: H0 G9 379 FGK)		

WATER (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
Sodium Benzoate (UNII: OJ245FE5EU)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53247-123-01	7.94 g in 1 PACKET; Type 0: Not a Combination Product	0 1/0 1/20 0 8	
2	NDC:53247-123-02	17 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 0 8	
3	NDC:53247-123-03	24 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 0 8	
4	NDC:53247-123-04	43 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 0 8	
5	NDC:53247-123-05	78 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 0 8	
6	NDC:53247-123-06	1 in 1 CARTON	0 1/0 1/20 0 8	
6		130 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:53247-123-07	1 in 1 CARTON	0 1/0 1/20 0 8	
7		181 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	0 1/0 1/20 0 8	

Labeler - Bob Barker Company Inc. (058525536)

Revised: 1/2020 Bob Barker Company Inc.