BEE SMART- sodium monofluorophosphate paste, dentifrice Dabur India Limited

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 Ingredients:

Sodium Monofluorophosphate 0.76%

(Total Fluoride Content – 1000 ppm Approx.)

Purpose

Anticavity

Uses:

Regular brushing with Fluoride toothpaste helps protect teeth and roots against cavities.

Warnings:

Keep out of reach of children under 6 years of age.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

	Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician.
Children under 6 yrs	To minimize swallowing use a pea-sized amount and supervise brushing until good habits are
Children under 2 yrs	established. Ask a dentist or physician

Ingredients:

Calcium Carbonate, Water, Sorbitol, Precipitated Silica, Sodium Lauryl Sulphate, Flavor, Sodium Carboxy Methyl Cellulose, Sodium Silicate, Tetra Sodium Pyrophosphate, Sodium Saccharin, Methyl Paraben, Titanium Dioxide, Poly Ethylene Glycol 400, Propyl Paraben.

Principal Display Panel – Carton Label

Bee Smart™ QUALITY & VALUE

TOOTHPASTE With Fluoride Anticavity Protection

Fresh Mint Flavor

NET WT 6.4 OZ (181g)



Principal Display Panel – Tube Label

Bee Smart[™] QUALITY & VALUE

TOOTHPASTE With Fluoride Anticavity Protection

Fresh Mint Flavor

NET WT 6.4 OZ (181g)



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Drug Facts	Drugs Facts (Contin	4 2 2	
Active Ingredients: Purpose Sodium Monofluorophosphate 0.76%Anticavity (Total Fluoride Content - 1000 ppm Approx.)	Directions: Adults and children 2 years and older.	Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician	by 5, Inc. 0,6401 Sinc.col MH/52 .on crimp
Uses: Regular brushing with Fluoride toothpaste helps protect teeth and roots against cavities.	Children under 6 yrs	To minimize swallowing use a pea-sized amount and supervise brushing until good habits are established. Ask a dentist or physician.	ributed roducts ngs, MC nroducts we in inducts wh/cos/p wh/cos/p
Warnings: Keep out of reach of children under 6 years of age. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.	Ingredients: Calcium Carbonate, Wat Carboxy Methyl Cellulos Paraben, Titanium Dioxi	Distri CSI Pro CSI Pro Sprind Www.csipring www.csipring c.no. DNH Exp. Date & E	

BEE SMART

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68747-6033
Route of Administration	DENTAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	7.6 mg in 1 g		

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SO DIUM (UNII: SB8ZUX40TY)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Character	ristics					
Color		Scor	re			
Shape		Size	Size			
Flavor	MINT (MINT)	Imp	mprint Code			
Contains						
Packaging		NF 1				
# Item Code	Package Description	Marketin	Marketing Start Date		Marketing End Date	
1 NDC:68747-6033-1	1 in 1 CARTON					
1	181 g in 1 TUBE					
-						
Marketing Info	rmation					
	rmation Application Number or Monog	raph Citation	Marketing Start	Date	Marketing End Date	

Labeler - Dabur India Limited (650319218)

Establishment

Name	Address	ID/FEI	Business Operations
Dabur India Limited		650319218	MANUFACTURE(68747-6033)

Revised: 8/2008

Dabur India Limited