

**FRESHMINT ANTICAVITY FLUORIDE GEL TOOTHPASTE- fluoride toothpaste 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.*

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**FRESHMINT®  
ANTICAVITY FLUORIDE GEL TOOTHPASTE**

**NET WT. 6.4 OZ**

**(181 GRAMS)**

**DRUG FACTS:**

**ACTIVE INGREDIENT**

Sodium fluoride - 0.22% (0.1% w/v fluoride ion)

**PURPOSE**

Anticavity.

**USE**

Helps protect against cavities.

**WARNINGS**

Keep out of 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.

**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 physician.

**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**

Treated Water, Sorbitol, Carbopol, Sodium Lauryl Sulphate, Flavor, Poly Ethylene Glycol 1500, Sodium Saccharin, Precipitated Silica, Sodium Carboxy Methyl Cellulose, Methyl Paraben, Propyl Paraben.

Product of India

Exclusive Distributor  
New World Imports, Inc.  
160 Athens Way  
Nashville, TN 37228.

Expires: 3 years from the Date of Mfg.

C. No. DNH/COS/DNH/52Mfg.  
Date & Batch No. on crimp.

**24.06.2009**

**FRESHMINT ANTICAVITY FLUORIDE GEL TOOTHPASTE**

**ACTIVE INGREDIENT: SODIUM FLUORIDE - 0.22 %  
(0.1% w/v fluoride Ion)**

**SR. NO. INGREDIENTS**

1. Treated water
2. Sorbitol
3. Carbopol
4. Sodium lauryl sulphate
5. Flavor
6. Polyethylene glycol 1500
7. Sodium saccharin
8. Precipitated Silica
9. Sodium Carboxy Methyl Cellulose
10. Methyl Paraben
11. Propyl Paraben

Principal Display Panel

Tube Label

**freshmint®**

*ANTICAVITY FLUORIDE GEL TOOTHPASTE*

NET WT. 6.4 OZ

(181 GRAMS)



**FRESHMINT ANTICAVITY FLUORIDE GEL TOOTHPASTE**

fluoride toothpaste paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68747-6027
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.2 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (MINT)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68747-6027-1	181 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/25/2009	

**Labeler** - Dabur India Limited (650319218)**Establishment**

Name	Address	ID/FEI	Business Operations
Dabur India Limited		650319218	MANUFACTURE

