FRESHMINT PREMIUM ANTICAVITY- sodium fluoride 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 INGREDIENT:

Sodium Fluoride - 0.243% (0.15% w/v fluoride ion)

PURPOSE:

Anticavity

USES:

Helps protect teeth and roots against cavities.

WARNINGS:

Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.

DIRECTIONS:

- Adults and children 2 years & older: Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. Do not swallow. To minimize swallowing use a pea-sized amount in children under 6 years of age. Supervise children's brushing until good habits are established.
- Children under 2 years: Ask a dentist.

INACTIVE INGREDIENTS:

Sorbitol, Silica, Treated Water (Aqua), Glycerin, Polyethylene Glycol 1500, Sodium Lauryl Sulphate, Flavor, Titanium Dioxide, Cellulose Gum, Carrageenan, Trisodium Orthophosphate, Sodium Saccharin, Sodium Benzoate, Tetrasodium Pyrophosphate, Methylparaben, Propylparaben, Color: FD & C Blue # 1.

Principal Display Panel – Tube Label

ADA

Accepted

American

Dental

Association[®]

freshmint[®]

Premium Anticavity Toothpaste

NET WT. 0.85 oz





The ADA's Council on Scientific Affairs' Acceptance of Freshmint Premium Anticavity Toothpaste is based on its finding that the product is effective in helping to prevent or reduce tooth decay when used as directed.

- Council on Scientific Affairs, American Dental Association.

DRUG FACTS:

ACTIVE INGREDIENT: PURPOSE:

WARNINGS: Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.

DIRECTIONS: • Adults and children 2 years & older: Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. Do not swallow. To minimize swallowing use a pea-sized amount in children under 6 years of age. Supervise children's brushing until good habits are established. • Children under 2 years: Ask a dentist.

INACTIVE INGREDIENTS: Sorbitol, Silica, Treated Water (Aqua), Glycerin, Polyethylene Glycol 1500, Sodium Lauryl Sulphate, Flavor, Titanium Dioxide, Cellulose Gum, Carrageenan, Trisodium Orthophosphate, Sodium Saccharin, Sodium Benzoate, Tetrasodium Pyrophosphate, Methylparaben, Propylparaben, Color: FD & C Blue # 1.





FRESHMINT PREMIUM ANTICAVITY

sodium fluoride paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:68747-6038	
Route of Administration	DENTAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (FLUORIDE ION)	FLUORIDE ION	2.43 mg in 1 g	

Inactive Ingredients				
Ingredient Name	Strength			
SORBITOL				
SILICON DIO XIDE				
WATER				
GLYCERIN				
POLYETHYLENE GLYCOL 1500				

SODIUM LAURYL SULFATE	
TITANIUM DIO XIDE	
CARBO XYMETHYLCELLULO SE SODIUM	
CARRAGEENAN	
SO DIUM PHO SPHATE, TRIBASIC, DO DECAHYDRATE	
SACCHARIN SO DIUM DIHYDRATE	
SODIUM BENZOATE	
SODIUM PYROPHO SPHATE	
METHYLPARABEN	
PROPYLPARABEN	
FD&C BLUE NO. 1	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (MINT)	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68747-6038-1	24 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR		0 1/0 1/20 13	

Labeler - Dabur India Limited (650319218)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dabur India Limited		650599231	MANUFACTURE(68747-6038)	

Revised: 8/2008 Dabur India Limited