

FRESHMINT SENSITIVE 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.

Sensodyne®

Drug Facts:

ACTIVE INGREDIENT

Potassium Nitrate - 5 %
Sodium Fluoride - 0.24 %

PURPOSE

Antihypersensitivity
Anticavity

USES

- builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact
- aids in the prevention of dental cavities

WARNINGS

When using this product do not use longer than 4 weeks unless recommended by a dentist or doctor.

Stop and ask a dentist if problem persists or worsens. Sensitive teeth may indicate a serious problem that may require prompt care by a dentist. Keep out of reach of children.

If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.

DIRECTIONS

Adults and children 12 years and older

Brush teeth for at least one minute, preferably after each meal, or at least twice a day, or as directed by your dentist. Be sure to brush sensitive areas

Children under 12 years of age

Consult a dentist or doctor.

Other information

Store In a cool dry place.

INACTIVE INGREDIENTS: Sorbitol, Silica, Treated Water, Poly Ethylene Glycol 1500, Sodium Lauryl Sulphate, Glycerin, Flavor, Sodium Carboxy Methyl Cellulose, Titanium Dioxide, Tri Sodium Ortho Phosphate, Sodium Saccharin, Sodium Benzoate, Methyl Paraben, Propyl Paraben, Color D & C Yellow # 10, FD & C Blue # 1.

Principal Display Panel - NET WT. 4.3 OZ (122g)

Freshmint Sensitive Toothpaste Tube Label
freshmint®

Sensitive Toothpaste

NET WT. 4.3 OZ (122g)

Anti-cavity Fluoride Tootpaste for Sensitive

***Compare to the Active Ingredients of Sensodyne® Fresh Mint**



This product is not manufactured or distributed by GlaxoSmithKline, owner of the registered trademark Sensodyne®.

Drug Facts:		Drug Facts (Continued)	
ACTIVE INGREDIENTS: Potassium Nitrate - 5 % Sodium Fluoride - 0.24 %	PURPOSE: Anti-hypersensitivity Anticavity	If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.	
USES: • helps increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact • aids in the prevention of dental cavities		DIRECTIONS	
WARNINGS: When using this product do not use longer than 4 weeks unless recommended by a dentist or doctor. Stop and ask a dentist if problem persists or worsens. Sensitive teeth may indicate a serious problem that may require prompt care by a dentist. Keep out of reach of children.		Adults and children 12 years and older	Brush teeth for at least one minute, preferably after each meal, or at least twice a day, or as directed by your dentist. Be sure to brush sensitive areas.
INACTIVE INGREDIENTS: Sorbitol, Silica, Treated Water, Poly Ethylene Glycol 1500, Sodium Lauryl Sulphate, Glycerin, Flavor, Sodium Carboxy Methyl Cellulose, Titanium Dioxide, Tin Sodium Ortho Phosphate, Sodium Saccharin, Sodium Borosulfate, Methyl Paraben, Propyl Paraben, Color: D & C Yellow #10, FD & C Blue #1.		Children under 12 years of age	Consult a dentist or doctor.
Product of India, Exclusive Distributor: New World Imports, Inc. 190 Athens Way, Nashville, TN 37226.		Other information	Store in a cool, dry place.
			Expires: 2 years from the Date of Mfg.

C.No. DSHVCS09M102
Mfg. Date & Batch No. on carton.

Freshmint Sensitive Toothpaste Carton Label
freshmint[®]

Sensitive Toothpaste

NET WT. 4.3 OZ (122g)

Anti-cavity Fluoride Toothpaste for Sensitive
***Compare to the Active Ingredients of Sensodyne[®] Fresh Mint**



FRESHMINT SENSITIVE TOOTHPASTE

fluoride toothpaste paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68747-6031
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.4 mg in 1 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM NITRATE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	white (white)	Score	
Shape		Size	
Flavor	MINT (MINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68747-6031-1	122 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

Revised: 8/2008

Dabur India Limited