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.

Sens o dyne[®]

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®

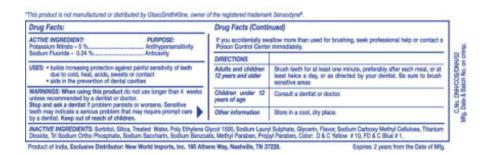
Sensitive Toothpaste

NET WT. 4.3 OZ (122g)

Anti-cavity Fluoride Tootpaste for Sensitive

*Compare to the Active Ingredients of Sensodyne $^{\circledR}$ Fresh Mint





Freshmint Sensitive Toothpaste Carton Label freshmint®

Sensitive Toothpaste

NET WT. 4.3 OZ (122g)

Anti-cavity Fluoride Tootpas te for Sens itive *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 DIO XIDE (UNII: ETJ7Z6 XBU4) | | |
| WATER (UNII: 059QF0KO0R) | | |
| POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A) | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311) | | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | | |
| SO DIUM PHO SPHATE, TRIBASIC, DO DECAHYDRATE (UNII: B70850 QPHR) | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | |
| METHYLPARABEN (UNII: A218 C7H19 T) | | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | | |

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

| I | 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