

DAWNMIST - sodium fluoride paste
Donavan

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.

Dawnmist toothpaste

sodium fluoride 0.22 % anticavity

calcium carbonate, water, sorbitol, silica, sodium lauryl sulphate, flavor, carboxyl methyl cellulose, sodium benzoate, sodium saccharin, potassium nitrate, menthol

adults and children 2 yrs. and older: 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 established.

children under 2 years: ask a dentist or physician.

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keep out of reach of children under 6 years of age. if you accidentally swallow more than used for brushing seek professional assistance or contact a poison control center immediately.

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expiration date: expiration date and batch no. on crimp of tube.

dawnmist anticavity fluoride toothpaste.

 <p>Cavity Fighting Formula Fresh Minty Taste</p>	 <p>DawnMist[®] Anticavity Fluoride Toothpaste</p>	<p>Net Wt. 6.4 OZ. (181.4g)</p>
<p>DRUG FACTS Active Ingredient: Sodium Fluoride 0.22%..... Purpose: Anticavity Use: Aids in the prevention of dental cavities. Warning: <i>Keep out of reach of children under 6 years of age.</i> If you accidentally swallow more than used for brushing seek professional assistance or contact a Poison Control Center immediately. Directions: Adults and children 2 yrs. and older: 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 established. Children Under 2 years: Ask a dentist or physician.</p>	<p>Inactive Ingredients: Calcium Carbonate, Water, Sorbitol, Silica, Sodium Lauryl Sulphate, Flavor, Carboxy Methyl Cellulose, Sodium Benzoate, Sodium Saccharin, Potassium Nitrate, Menthol. Expiration Date: Expiration Date & Batch No. on Crimp of Tube.</p> <p>Manufactured for: Donovan Industries, Inc. Tampa, FL 33626-3061 800.334.4404 www.dawnmist.com</p> <p>DawnMist[®] E.C.No.:DD/COS/DD/C/52 MADE IN INDIA</p>	<p>Reorder No. RTP64</p>  <p>7 57709 00263 6</p> <p>Rev. No. 09/11/15163</p>

DAWNMIST

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55504-4341
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sodium fluoride (UNII: 8ZYQ1474W7) (fluoride ion - UNII:Q80VPU408O)	sodium fluoride	39.9 g in 181.4 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
PEPPERMINT (UNII: V95R5KMY2B)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7)	
MENTHOL (UNII: L7T10EIP3A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEPPERMINT (peppermint flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55504-4341-8	181.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/01/2011	

