

SODIUM FLUORIDE- toothpaste cream
DUKAL CORPORATION

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

Active ingredient

Sodium fluoride 0.22%

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings Section

Warnings

Keep out of reach of children

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

Directions

Adults and children 2 years: 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 years:** To minimize swallowing use a pea sized amount and supervise brushing until good habits are established.

Children under 2 years: Ask a doctor or physician.

Inactive ingredients

calcium carbonate, water, sorbitol, sodium lauryl sulfate, silica, carboxymethyl cellulose, flavor, potassium nitrate, sodium benzoate, sodium saccharin, menthol

Expiration date

Expiration date & batch No. on crimp of tube

Principal Display Panel - DawnMist Fluoride Toothpaste 0.6 OZ Tube Label

DawnMist[®]

NDC: 65517-2000-0

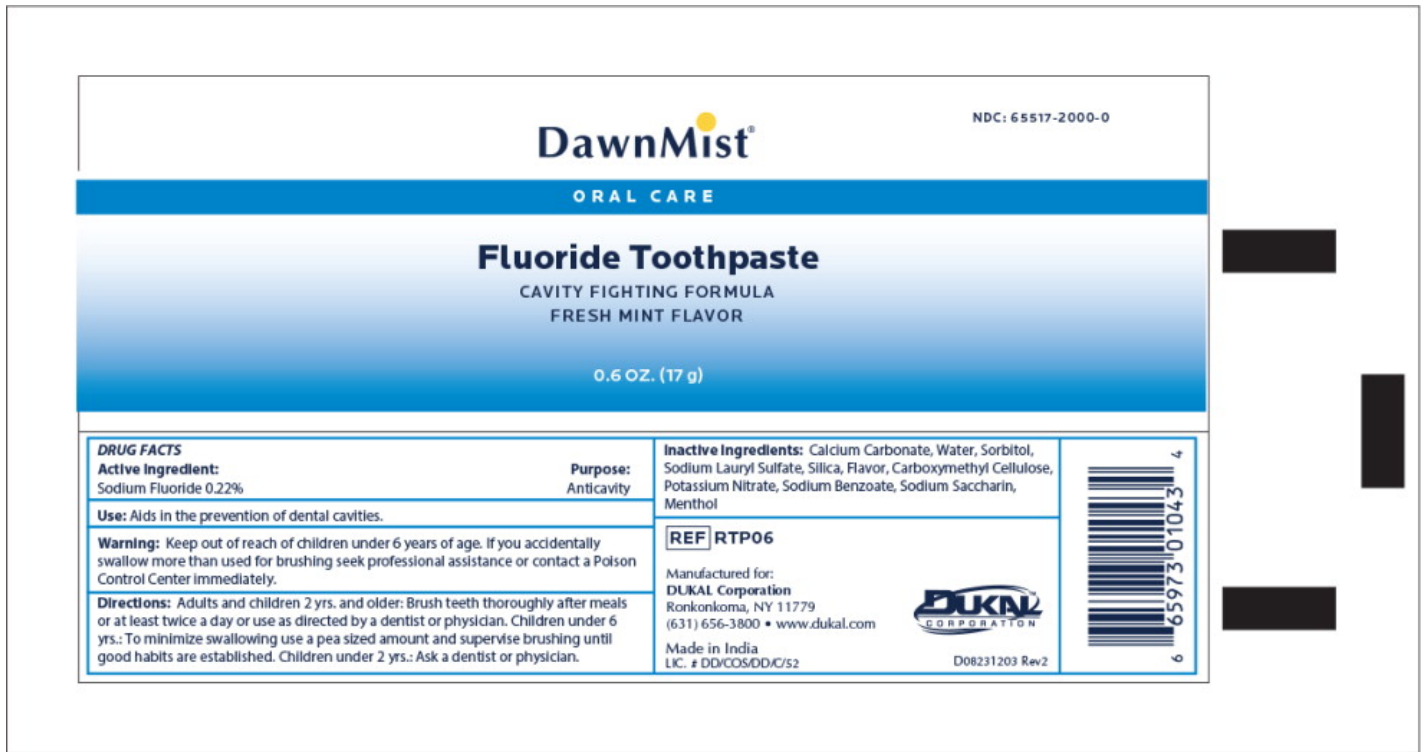
ORAL CARE

Fluoride Toothpaste

CAVITY FIGHTING FORMULA

FRESH MINT FLAVOR

0.6 OZ. (17 g)



SODIUM FLUORIDE

toothpaste cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65517-2000
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22 g in 100 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)	

POTASSIUM NITRATE (UNII: RU45X2JN0Z)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MENTHOL (UNII: L7T10EP3A)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65517-2000-0	17 g in 1 TUBE; Type 0: Not a Combination Product	02/19/2015	
2	NDC:65517-2000-1	24 g in 1 TUBE; Type 0: Not a Combination Product	02/19/2015	
3	NDC:65517-2000-2	42 g in 1 TUBE; Type 0: Not a Combination Product	02/19/2015	
4	NDC:65517-2000-3	78 g in 1 TUBE; Type 0: Not a Combination Product	02/19/2015	
5	NDC:65517-2000-4	1 in 1 BOX	02/19/2015	
5		42 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:65517-2000-5	1 in 1 BOX	02/19/2015	
6		78 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:65517-2000-6	1 in 1 BOX	02/19/2015	
7		135 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:65517-2000-7	1 in 1 BOX	02/19/2015	
8		181 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/13/2013	

Labeler - DUKAL CORPORATION (791014871)