SODIUM FLUORIDE- toothpaste cream
DUKAL LLC

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 accidently 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

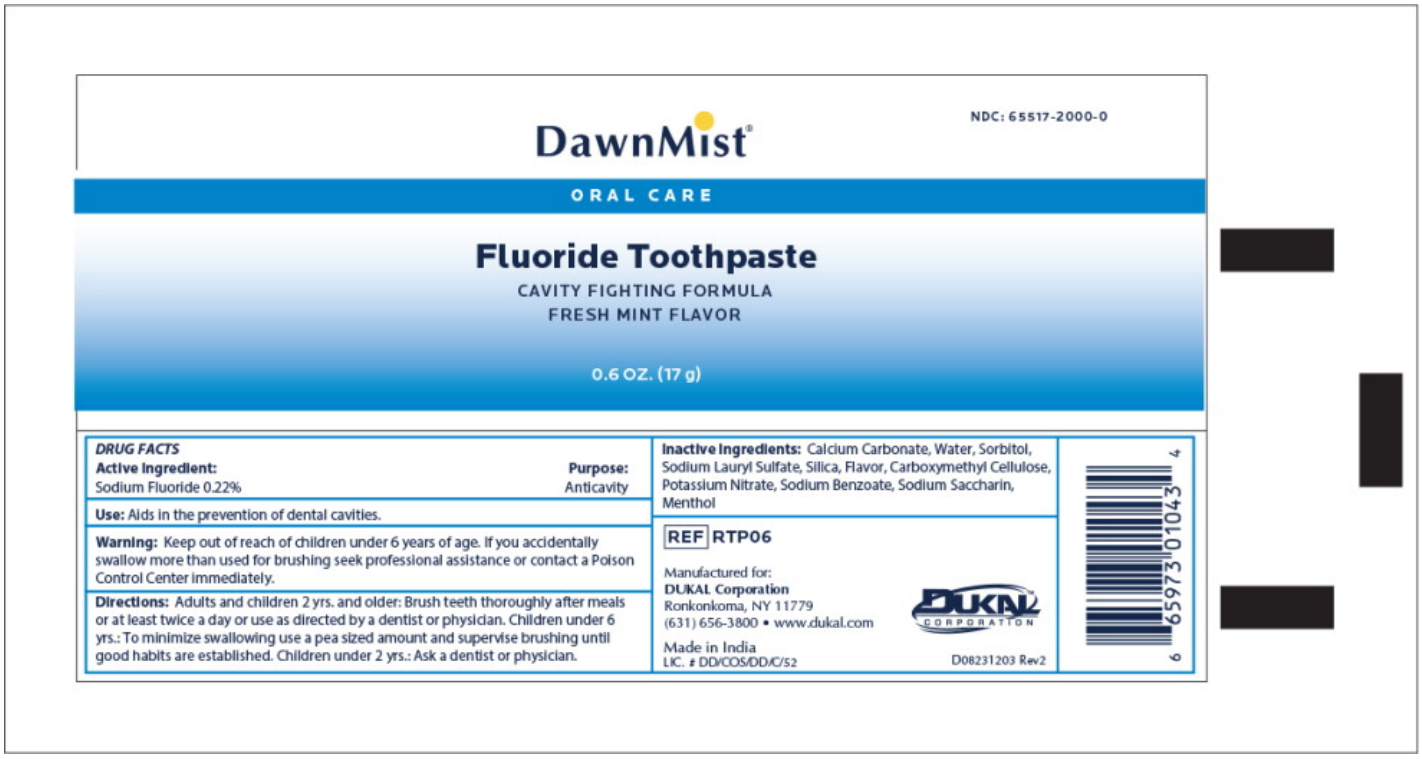
ORAL CARE

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: L7T10EIP3A)	

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 Drug	M022	11/13/2013	

Labeler - DUKAL LLC (791014871)

Revised: 10/2023 DUKAL LLC