

DAWNMIST FLUORIDE- sodium fluoride paste
Dukal LLC

DawnMist Fluoride Toothpaste

DawnMist Fluoride Toothpaste

Active Ingredient

Sodium Monofluorophosphate 0.76%

Purpose

Anticavity

Use

Aids in the prevention of dental cavities.

Warning:

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.

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 dentist or physician.

Inactive Ingredients

Sorbitol, Silica, Water, Sodium Lauryl Sulfate, Xanthan Gum, Sodium Benzoate, Titanium Dioxide, Mentha Piperita (Peppermint Oil), Sodium Saccharin

DawnMist Fluoride Toothpaste 0.6oz/17g (65517-2018-0)

DawnMist™ NDC: 65517-2018-0

ORAL CARE

Gel Fluoride Toothpaste
 CAVITY FIGHTING FORMULA
 FRESH MINT FLAVOR
 0.6 OZ. (17g)

DawnMist[®]		NDC: 65517-2018-0
ORAL CARE		
Gel Fluoride Toothpaste		
CAVITY FIGHTING FORMULA FRESH MINT FLAVOR		
0.6 OZ. (17 g)		
<p>DRUG FACTS</p> <p>Active Ingredient: Sodium Fluoride 0.22%</p> <p>Use: Aids in the prevention of dental cavities.</p> <p>Warning: 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.</p> <p>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 yrs.: Ask a dentist or physician.</p>	<p>Purpose: Anticavity</p> <p>Inactive Ingredients: Sorbitol, Silica, Water, Sodium Lauryl Sulfate, Carboxymethyl Cellulose, Sodium Saccharine, Sodium Benzoate, Titanium Dioxide, Flavor, Menthol, PEG1500, Silica Absil-100</p> <p>REF TP1295</p> <p>Manufactured for: DUKAL Corporation Ronkonkoma, NY 11779 (631) 656-3800 • www.dukal.com</p> <p>Made in India LIC. # DD/COS/DD/C/52</p>	
		 D10101201 Rev2

DAWNMIST FLUORIDE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65517-2018
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PEPPERMINT OIL (UNII: AV092KU4JH)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	

CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65517-2018-0	17 g in 1 TUBE; Type 0: Not a Combination Product	01/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/30/2014	

Labeler - Dukal LLC (791014871)

Revised: 10/2023

Dukal LLC