

DAWNMIST FLUORIDE- sodium fluoride paste
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 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)

DRUG FACTS

Active Ingredient:

Sodium Fluoride 0.22%

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 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.

Inactive Ingredients: Sorbitol, Silica, Water, Sodium Lauryl Sulfate, Carboxymethyl Cellulose, Sodium Saccharine, Sodium Benzoate, Titanium Dioxide, Flavor, Menthol, PEG1500, Silica Absil-100

REF TP1295

Manufactured for:
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Made in India
LIC. # DD/COS/DD/C/52



D10101201 Rev2



DAWNMIST FLUORIDE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65517-20 18
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	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 final	part355	01/30/2014	

Labeler - Dukal Corporation (791014871)

Revised: 9/2018

Dukal Corporation