DAWNMIST FLUORIDE- sodium fluoride paste
Dukal LLC

DawnMist Gel Fluoride Toothpaste

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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 accidently swallow more than used for brushing seek professional assistance or contact a Poison Control 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 peas sized amount and supervisor brushing until good habits are established.

Children under 2 years: Ask a dentist or physician

Inactive Ingredient

Sorbitol, Water, Silica, Sodium Lauryl Sulphate, PEG1500, Flavor, Carboxymethyl Cellulose, Sodium Benzoate, Sodium Saccharin

Principal Display Panel - DawnMist Gel Fluoride Toothpaste 2.75 oz Tube Label

DawnMist®

NDC: 65517-2017-0

ORAL CARE

Gel Fluoride Toothpaste

CAVITY FIGHTING FORMULA

FRESH MINT FLAVOR

2.75 OZ. (78 g)

DAWNMIST FLUORIDE

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65517-2017
Route of Administration	DENTAL		

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65517-2017-0	78 g in 1 TUBE; Type 0: Not a Combination Product	07/14/2017	06/12/2026
2	NDC:65517-2017-1	17 g in 1 TUBE; Type 0: Not a Combination Product	07/14/2017	07/25/2026
3	NDC:65517-2017-2	24 g in 1 TUBE; Type 0: Not a Combination Product	07/14/2017	07/25/2026
4	NDC:65517-2017-3	43 g in 1 TUBE; Type 0: Not a Combination Product	07/14/2017	07/25/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/17/2014	07/25/2026

Labeler - Dukal LLC (791014871)

Revised: 7/2024 Dukal LLC