

DAWNMIST- toothpaste paste, dentifrice
Dukal LLC

65517-2005 - DawnMist Fluoride Toothpaste

DawnMist Fluoride Toothpaste

Sodium Fluoride 0.22%

Anticavity

Aids in the prevention of dental cavities.

Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Do not swallow, supervise children as necessary until capable of using without supervision. Instruct Children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Children under 6 years of age: Do not use unless directed by a doctor or dentist.

Calcium Carbonate, Carboxymethylcellulose Sodium, Flavor, Guaraprollose, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water

DawnMist

Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2005-0

Dukal

0.6oz (17g)



DawnMist

Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2005-0

Dukal

0.6 oz (17g)

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.22%.....	Anticavity

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Inactive Ingredients Calcium Carbonate, Carboxymethylcellulose Sodium, Flavor, Guaraprollose, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water

REF RTPO6

Dukal

Manufactured for: **Dukal, LLC**
Ronkonkoma, NY 11779
1 (800) 243-0741 • dukal.com

Made in China
Rev 5



DawnMist

Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2005-1

Dukal

0.85oz (24g)



DawnMist

Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2005-1

Dukal
0.85 oz (24g)

Drug Facts

Active Ingredient

Sodium Fluoride 0.22%

Purpose

Anticavity

Use Aids in the prevention of dental cavities.

Warnings Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions Do not swallow, supervise children as necessary until capable of using without supervision. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Children under 6 years of age: Do not use unless directed by a doctor or dentist.

Inactive Ingredients Calcium Carbonate, Carboxymethylcellulose Sodium, Flavor, Guaraprollose, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water

REF RTPO85



Manufactured for: **Dukal, LLC**
Ronkonkoma, NY 11779
1 (800) 243-0741
dukaL.com
Made in China
Rev 5



DawnMist
Fluoride Toothpaste
FRESH MINT FLAVOR
NDC: 65517-2005-2
Dukal
1.5oz (43g)



DawnMist

Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2005-2

Dukal
1.5 oz (43g)

Drug Facts

Active Ingredient

Sodium Fluoride 0.22%

Purpose

Anticavity

Use Aids in the prevention of dental cavities.

Warnings Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions Do not swallow, supervise children as necessary until capable of using without supervision. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Children under 6 years of age: Do not use unless directed by a doctor or dentist.

Inactive Ingredients Calcium Carbonate, Carboxymethylcellulose Sodium, Flavor, Guaraprollose, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water

REF RTP15



Manufactured for: **Dukal, LLC**
Ronkonkoma, NY 11779
1(800)243-0741 • dukal.com
Made in China
Rev 4



DawnMist
Fluoride Toothpaste
FRESH MINT FLAVOR
NDC: 65517-2005-3
Dukal
2.75oz (78g)



DawnMist

**Fluoride
Toothpaste**

FRESH MINT FLAVOR

NDC: 65517-2005-3

Dukal
2.75 oz (78g)

Drug Facts

Active Ingredient

Sodium Fluoride 0.22%.....

Purpose

Anticavity

Use Aids in the prevention of dental cavities.

Warnings Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

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Inactive Ingredients Calcium Carbonate, Carboxymethylcellulose Sodium, Flavor, Guaraprollose, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water

REF RTP27



Manufactured for: **Dukal, LLC**
Ronkonkoma, NY 11779
1 (800) 243-0741 • dukal.com
Made in China
Rev 4



DawnMist
Fluoride Toothpaste
FRESH MINT FLAVOR
NDC: 65517-2005-4
Dukal
4.75oz (134g)



DawnMist

**Fluoride
Toothpaste**

FRESH MINT FLAVOR

NDC: 65517-2005-4

Dukal
4.75 oz (134g)

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.22%.....	Anticavity

Use Aids in the prevention of dental cavities.

Warnings Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

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Inactive Ingredients Calcium Carbonate, Carboxymethylcellulose Sodium, Flavor, Guaraprollose, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water

REF RTP47B

Manufactured for: **Dukal, LLC**
Ronkonkoma, NY 11779
1 (800) 243-0741 • dukal.com
Made in China
Rev 4



DawnMist
Fluoride Toothpaste
FRESH MINT FLAVOR
NDC: 65517-2005-5
Dukal
6.4oz (181g)



Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2005-5

Dukal
6.4oz (181g)

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.22%	Anticavity

Use Aids in the prevention of dental cavities.

Warnings Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

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directed by a dentist or doctor. Children under 6 years of age: Do not use unless directed by a doctor or dentist.

Inactive Ingredients Calcium Carbonate, Carboxymethylcellulose Sodium, Flavor, Guaraprollose, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water

REF RTP64

Manufactured for: Dukal, LLC
Ronkonkoma, NY 11779
1 (800) 243-0741 • dukal.com
Made in China
Rev 4



DAWNMIST

toothpaste paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65517-2005
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GUARAPROLOSE (1300 MPA.S AT 1%) (UNII: 1530WMS90S)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65517-2005-0	17 g in 1 TUBE; Type 0: Not a Combination Product	03/25/2024	
2	NDC:65517-2005-1	24 g in 1 TUBE; Type 0: Not a Combination Product	03/25/2024	
3	NDC:65517-2005-2	43 g in 1 TUBE; Type 0: Not a Combination Product	03/25/2024	
4	NDC:65517-2005-3	78 g in 1 TUBE; Type 0: Not a Combination Product	03/25/2024	
5	NDC:65517-2005-4	134 g in 1 TUBE; Type 0: Not a Combination Product	03/25/2024	
6	NDC:65517-2005-5	181 g in 1 TUBE; Type 0: Not a Combination Product	03/25/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	03/25/2024	

Labeler - Dukal LLC (791014871)

Revised: 2/2025

Dukal LLC