

**DAWNMIST GEL FLUORIDE- gel fluoride toothpaste gel, dentifrice  
Dukal LLC**

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**65517-2004 - DawnMist Gel Fluoride Toothpaste**

**DawnMist Gel 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.

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.

Carboxymethylcellulose Sodium, Flavor, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water, Xanthan Gum

DawnMist

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2004-1

Dukal

0.6oz (17g)



**DawnMist**

# Gel Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2004-1

**Dukal**

0.6 oz (17g)

**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** Carboxymethylcellulose Sodium, Flavor, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water, Xanthan Gum

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

REF GTP4654



LOT



DawnMist

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2004-2

Dukal

0.85oz (24g)



DawnMist

Gel Fluoride  
Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2004-2

Dukal  
0.85 oz (24g)

**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.

**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** Carboxymethylcellulose Sodium, Flavor, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water, Xanthan Gum

REF GTP4661



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



DawnMist

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2004-3

Dukal

1.5oz (43g)



**DawnMist**

# Gel Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2004-3

**Dukal**  
1.5 oz (43g)

### 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.

**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** Carboxymethylcellulose Sodium, Flavor, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water, Xanthan Gum

REF GTP4678



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

Made in China  
Rev 5



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DawnMist

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2004-0

Dukal

2.75oz (78g)



# Gel Fluoride Toothpaste

FRESH MINT FLAVOR

NDC: 65517-2004-0

**Dukal**  
2.75 oz (78g)

### 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.

**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** Carboxymethylcellulose Sodium, Flavor, Saccharin Sodium, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Water, Xanthan Gum

REF GTP4685

**Dukal**

Manufactured for: Dukal, LLC

Ronkonkoma, NY 11779

1 (800)243-0741 • dukal.com

Made in China

Rev 5



## DAWNMIST GEL FLUORIDE

gel fluoride toothpaste gel, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65517-2004
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.22 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

**SODIUM BENZOATE** (UNII: OJ245FE5EU)

**SORBITOL** (UNII: 506T60A25R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65517-2004-1	17 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2024	
2	NDC:65517-2004-0	78 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2024	
3	NDC:65517-2004-2	24 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2024	
4	NDC:65517-2004-3	43 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	05/01/2024	

**Labeler** - Dukal LLC (791014871)

Revised: 2/2025

Dukal LLC