

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

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.

Sorbitol, Hydrated Silica, Glycerin, Water, PEG-400, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Xanthan Gum, Sodium Saccharin

DawnMist NDC: 65517-2004-1

Oral Care

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

0.6 OZ. (17 g)

ORAL CARE

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

0.6 OZ. (17 g)

LOT



Drug Facts		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.
Active Ingredient Sodium Fluoride 0.22%.....	Purpose Anticavity	
Use Aids in the prevention of dental cavities.		Inactive Ingredients Sorbitol, Hydrated Silica, Glycerin, Water, PEG-400, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Xanthan Gum, Sodium Saccharin
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 ▶		Manufactured For: Dukal, LLC Ronkonkoma, NY 11779 dukal.com Made in China Dukal is a trademark registered in the US Patent & Trademark Office by Dukal, LLC

REF GTP4654



Rev4

DawnMist NDC: 65517-2004-2

Oral Care

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

0.85 OZ. (24 g)

DawnMist®

NDC: 65517-2004-2

ORAL CARE

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

0.85 OZ. (24 g)

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 Sorbitol, Hydrated Silica, Glycerin, Water, PEG-400, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Xanthan Gum, Sodium Saccharin

REF GTP4661

Manufactured For: Dukal, LLC

Ronkonkoma, NY 11779 | dukal.com

Made in China

Dukal is a trademark registered in the US Patent & Trademark Office by Dukal, LLC



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LOT

Rev4

DawnMist NDC: 65517-2004-3

Oral Care

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

1.5 OZ. (43 g)




DawnMist®

ORAL CARE

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

1.5 OZ. (43 g)

Drug Facts		REF GTP4678	Manufactured For: Dukal, LLC Ronkonkoma, NY 11779 dukal.com Made in China Dukal is a trademark registered in the US Patent & Trademark Office by Dukal, LLC
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 Sorbitol, Hydrated Silica, Glycerin, Water, PEG-400, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Xanthan Gum, Sodium Saccharin		 6 65973 01084 7	
		 Rev4	

DawnMist NDC: 65517-2004-0

Oral Care

Gel Fluoride Toothpaste

FRESH MINT FLAVOR


2.75 OZ. (78 g)

ORAL CARE

Gel Fluoride Toothpaste

FRESH MINT FLAVOR

2.75 OZ. (78 g)

Drug Facts		REF GTP4685 Manufactured For: Dukal, LLC Ronkonkoma, NY 11779 dukal.com Made in China Dukal is a trademark registered in the US Patent & Trademark Office by Dukal, LLC
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.		 6 65973 01085 4
Inactive Ingredients Sorbitol, Hydrated Silica, Glycerin, Water, PEG-400, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Xanthan Gum, Sodium Saccharin		

DAWNMIST GEL FLUORIDE

gel fluoride toothpaste gel, dentifrice

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

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: 3/2024

Dukal LLC