

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, Water, Sorbitol, PEG-400, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Hydroxypropyl Guar, Sodium Saccharin, Methylparaben, Propylparaben

DawnMist NDC: 65517-2005-0

Oral Care

Fluoride Toothpaste

FRESH MINT FLAVOR

0.6 OZ. (17 g)

NDC: 65517-2005-0

DawnMist®

ORAL CARE

Fluoride Toothpaste

FRESH MINT FLAVOR

0.6 OZ. (17 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 Calcium Carbonate, Water, Sorbitol, PEG-400, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Hydroxypropyl Guar, Sodium Saccharin, Methylparaben, Propylparaben

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 RTP06



Rev3

DawnMist NDC: 65517-2005-1

Oral Care

Fluoride Toothpaste

FRESH MINT FLAVOR


0.85 OZ. (24 g)

ORAL CARE

Fluoride Toothpaste

FRESH MINT FLAVOR

0.85 OZ. (24 g)

Drug Facts		REF RTP085
Active Ingredient	Purpose	 <p>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</p>
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 Calcium Carbonate, Water, Sorbitol, PEG-400, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Hydroxypropyl Guar, Sodium Saccharin, Methylparaben, Propylparaben		Rev3

DawnMist NDC: 65517-2005-2

Oral Care

Fluoride Toothpaste

FRESH MINT FLAVOR

1.5 OZ. (43 g)

DawnMist®

ORAL CARE

Fluoride Toothpaste

FRESH MINT FLAVOR

1.5 OZ. (43 g)

Drug Facts

Active Ingredient

Sodium Fluoride 0.22%.....Anticavity

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, Water, Sorbitol, PEG-400, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Hydroxypropyl Guar, Sodium Saccharin, Methylparaben, Propylparaben

REF RTP15

Manufactured For: **Dukat, LLC**
Ronkonkoma, NY 11779 | dukal.com
Made in China

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



Rev3

DawnMist NDC: 65517-2005-3

Oral Care

Fluoride Toothpaste

FRESH MINT FLAVOR

2.75 OZ. (78 g)

DawnMist®

ORAL CARE

Fluoride Toothpaste

FRESH MINT FLAVOR

2.75 OZ. (78 g)

Drug Facts		Inactive Ingredients Calcium Carbonate, Water, Sorbitol, PEG-400, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Hydroxypropyl Guar, Sodium Saccharin, Methylparaben, Propylparaben
Active Ingredient Sodium Fluoride 0.22%.....	Purpose Anticavity	
Use Aids in the prevention of dental cavities.		REF RTP27
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.		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



6 65973 01046 5
Rev3

DawnMist NDC: 65517-2005-4

Oral Care

Fluoride Toothpaste

FRESH MINT FLAVOR

4.75 OZ. (134 g)


DawnMist®

ORAL CARE

Fluoride Toothpaste

FRESH MINT FLAVOR

4.75 OZ. (134 g)

Drug Facts		Inactive Ingredients Calcium Carbonate, Water, Sorbitol, PEG-400, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Hydroxypropyl Guar, Sodium Saccharin, Methylparaben, Propylparaben REF RTP47B Manufactured For: Dukat, LLC Ronkonkoma, NY 11779 dukal.com Made in China Dukat is a trademark registered in the US Patent & Trademark Office by Dukat, 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.		 6 65973 01048 9 Rev3
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.		

DawnMist NDC: 65517-2005-5

Oral Care

Fluoride Toothpaste


FRESH MINT FLAVOR

6.4 OZ. (181 g)

Fluoride Toothpaste

FRESH MINT FLAVOR

6.4 OZ. (181 g)

Drug Facts		directed by a dentist or doctor. Children under 6 years of age: Do not use unless directed by a doctor or dentist.
Active Ingredient	Purpose	Inactive Ingredients Calcium Carbonate, Water, Sorbitol, PEG-400, Sodium Lauryl Sulfate, Hydrated Silica, Cellulose Gum, Flavor, Hydroxypropyl Guar, Sodium Saccharin, Methylparaben, Propylparaben
Sodium Fluoride 0.22%.....	Anticavity	
Use Aids in the prevention of dental cavities.		REF RTP64 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
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		 <p>6 65973 01049 6</p> <p>Rev3</p>

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:Q80VPU408O)	FLUORIDE ION	0.22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

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: 3/2024

Dukal LLC