

DAWNMIST GEL FLUORIDE TOOTH- sodium fluoride paste, dentifrice
Yangzhou SION Commodity Co.,Ltd

70766-014

Active ingredients

SODIUM FLUORIDE 0.22%(0.10 w/v Fluoride ion)

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Fluoride ion)</paragraph> <paragraph/>&lt;text xmlns="urn:hl7-org:v3">  
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Purpose

Anticavity

Uses

Aids in the prevention of dental cavities.

Warnings

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

Keep out of reach of children.

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 minimizing 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 a doctor.
- Children under 2 years of age: consult a doctor or dentist.

INACTIVE INGREDIENT

Sorbitol, Hydrated Silica, Glycerin, Water, PEG-400, Sodium Lauryl Sulfate, Cellulose Gum, Xanthan gum, flavor, Sodium Benzoate, Sodium saccharine

NDC: 65517-2004-3



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	SY12024 20270428 
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 01084 7 Rev4	
Inactive Ingredients Sorbitol, Hydrated Silica, Glycerin, Water, PEG-400, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Xanthan Gum, Sodium Saccharin			

DAWNMIST GEL FLUORIDE TOOTH

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-014
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-014-01	5 in 1 CARTON	04/29/2024	
1		144 in 1 BOX		
1		17 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70766-014-02	5 in 1 CARTON	04/29/2024	
2		144 in 1 BOX		
2		24 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70766-014-03	144 in 1 BOX	04/29/2024	
3		43 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:70766-014-04	144 in 1 BOX	04/29/2024	
4		78 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/04/2024	

Labeler - Yangzhou SION Commodity Co.,Ltd (546806042)

Registrant - Yangzhou SION Commodity Co.,Ltd (546806042)

Establishment			
Name	Address	ID/FEI	Business Operations
Yangzhou SION Commodity Co.,Ltd		546806042	manufacture(70766-014)