

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

70766-015 DawnMist

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

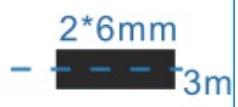
- Do not swallow, supervise children as necessary until capable of using without supervision. Instruct children under 12 years of age in good brushing and rinsing habits (to minimizing swallowing).
- Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at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

INACTIVE INGREDIENT

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



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 RTP06 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 Rev3
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 01043 4
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 FLUORIDE TOOTH			
sodium fluoride paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-015
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: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-015-01	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:70766-015-02	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:70766-015-03	144 in 1 BOX	04/29/2024	
3		43 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:70766-015-04	144 in 1 BOX	04/29/2024	
4		78 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:70766-015-05	60 in 1 BOX	04/29/2024	
5		135 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:70766-015-06	48 in 1 BOX	04/29/2024	
6		181.4 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(70766-015)

Revised: 4/2024

Yangzhou SION Commodity Co.,Ltd