

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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

70766-009

Active ingredients

Sodium Fluoride 0.22%(0.1 w/v Fluoride ion)

Purpose

anticavity toothpaste

Uses

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.

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 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 a physician.
- Children under 6 years of age: do not use unless directed by a doctor or dentist.

INACTIVE INGREDIENT

Calcium Carbonate, Sorbitol, Hydrated Silica, Water, PEG-8, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Hydroxypropyl Guar, Sodium Saccharin, Methylparaben, Propylparaben

AMERFRESH®

FLUORIDE TOOTHPASTE NET WT. 0.85oz (24g)

Drug Facts		Drug Facts(continued)
Active ingredient Sodium Fluoride 0.22% (0.1% w/v fluoride ion)..... Anticavity toothpaste	Purpose Anticavity toothpaste	<ul style="list-style-type: none"> • 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 a doctor. • Children under 6 years of age:Do not use unless directed by a doctor or dentist.
Use aids in the prevention of dental cavities		
Warning 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.		Inactive ingredients calcium carbonate,sorbitol,water,hydrated silica,PEG-8,sodium lauryl sulfate,cellulose gum,flavor,hydroxypropyl guar,sodium saccharin,methylparaben,propylparaben
Directions • do not swallow • supervise children as necessary until capable of using without supervision ▶		

Exclusive Distributor:AMERCARE Products Inc., Woodinville., WA 98072.
Made in China. Mfg.Date & Batch No.on Crimp.Exp.Date:3 years from date of Mfg.

AMERFRESH FLUORIDE

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-009-01	144 in 1 BOX	02/28/2022	
1		17 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70766-009-02	144 in 1 BOX	02/28/2022	
2		24 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70766-009-03	144 in 1 BOX	02/28/2022	
3		43 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:70766-009-04	144 in 1 BOX	02/28/2022	
4		78 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:70766-009-05	144 in 1 BOX	02/28/2022	
5		85 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:70766-009-06	144 in 1 BOX	02/28/2022	
6		142 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:70766-009-07	1000 in 1 BOX	02/28/2022	
7		7 g in 1 POUCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	02/28/2022		

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(70766-009)