

AMERFRESH FLUORIDE GEL- 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.

70766-008

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

Sorbitol, Hydrated Silica, Water, PEG-8, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Saccharin, Glycerin, anthan Gum, Sodium Benzoate, Cetylpyridinium Chloride.





AMERFRESH

FLUORIDE Gel TOOTHPASTE NET WT. 3 OZ (85g)

Drug Facts	Drug Facts(continued)
<p>Active ingredient Sodium Fluoride 0.22% (0.1% w/v fluoride ion)..... Anticavity toothpaste</p> <p>Use aids in the prevention of dental cavities</p> <p>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.</p> <p>Directions • do not swallow • supervise children as necessary until capable of using without supervision ▶</p>	<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. <p>Inactive ingredients sorbitol, hydrated silica , water, PEG-8, sodium lauryl sulfate,cellulose gum,flavor,sodium saccharin,glycerin,xanthan gum,sodium benzoate, cetylpyridinium chloride</p>

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 GEL

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-008-01	144 in 1 BOX	02/28/2022	
1		17 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70766-008-02	144 in 1 BOX	02/28/2022	
2		24 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70766-008-03	144 in 1 BOX	02/28/2022	

3		43 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:70766-008-04	144 in 1 BOX	02/28/2022	
4		78 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:70766-008-05	144 in 1 BOX	02/28/2022	
5		85 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:70766-008-06	144 in 1 BOX	02/28/2022	
6		142 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:70766-008-07	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(70766-008)

Revised: 2/2023

Yangzhou SION Commodity Co.,Ltd