

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

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**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.

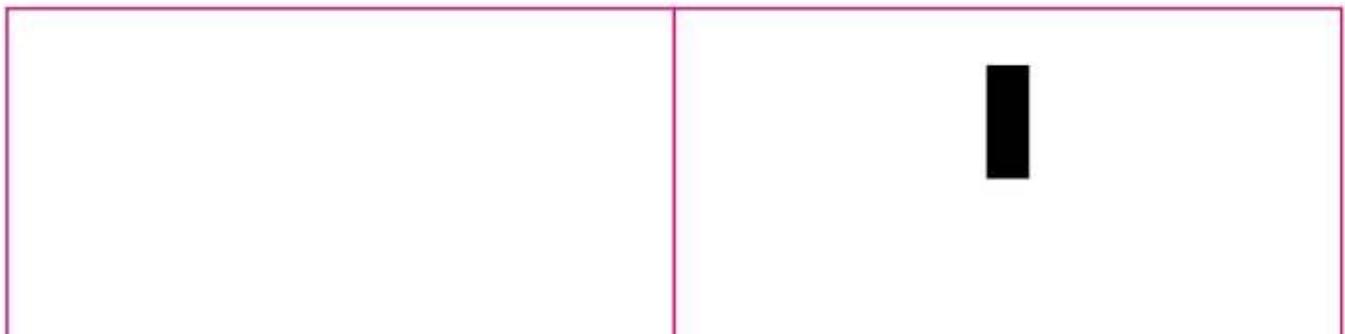
Keep out of reach of children.

**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.



# AMER<sup>®</sup>FRESH

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

<b>Drug Facts</b>	<b>Drug Facts(continued)</b>
<b>Active ingredient</b> Sodium Fluoride 0.22% (0.1% w/v fluoride ion)..... Anticavity toothpaste	<ul style="list-style-type: none"> <li>• Instruct children under 12 years of age in good brushing and rinsing habits(to minimize swallowing).</li> <li>• 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.</li> <li>• Children under 6 years of age:Do not use unless directed by a doctor or dentist.</li> </ul>
<b>Use</b> aids in the prevention of dental cavities	<b>Inactive ingredients</b> sorbitol, hydrated silica ,water, PEG-8,sodium lauryl sulfate,cellulose gum,flavor,sodium saccharin,glycerin,xanthan gum,sodium benzoate, cetylpyridinium chloride
<b>Warning</b> <b>Keep out of the reach of children under 6 years of age.</b> If more than used for brushing is accidentally swallowed,get medical help or contact a Poison Control Center immediately.	
<b>Directions</b> • 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 GEL

sodium fluoride paste, dentifrice

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>CETYLPYRIDINIUM CHLORIDE</b> (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 Drug	M021	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: 12/2024

Yangzhou SION Commodity Co.,Ltd