

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

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**70766-001 Amerfresh Fluoride Toothpaste**

**Active ingredients**

Sodium monofluorophosphate 0.76%(0.1 w/v Fluoride ion)

**Purpose**

anticavity

**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,water,sorbitol,hydrated silica,sodium lauryl sulfate,sodium carboxymethyl cellulose,flavor,sodium saccharine,polymethylene glycol,guar gum,methylisothiazolinone.

# AMERFRESH®

FLUORIDE TOOTHPASTE NET W.T. 0.6oz (17g)

Drug Facts		Drug Facts(continued)
<b>Active ingredient</b> Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion).....	<b>Purpose</b> 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>Warning</b> 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.		<b>Inactive ingredients</b> calcium carbonate,water,sorbitol, hydrated silica,sodium lauryl sulfate,sodium carboxymethyl cellulose,flavor,sodium saccharine, polymethylene glycol, guar gum, methylisothiazolinone.
<b>Directions</b> • do not swallow • supervise children as necessary until capable of using without supervision ▶		

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

## AMERFRESH

sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70766-001
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.76 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GUAR GUM</b> (UNII: E89I1637KE)	
<b>POTASSIUM SODIUM SACCHARATE</b> (UNII: 73U34YC90U)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>METHYLENE GLYCOL</b> (UNII: 6Z20YM9257)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>DISODIUM CARBOXYMETHYLARSONATE</b> (UNII: T9HTL93NB7)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-001-01	144 in 1 BOX	05/25/2016	
1		17 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70766-001-02	144 in 1 BOX	05/25/2016	
2		24 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70766-001-03	144 in 1 BOX	05/25/2016	
3		43 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:70766-001-04	144 in 1 BOX	05/25/2016	
4		78 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:70766-001-05	144 in 1 BOX	06/18/2016	
5		85 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:70766-001-06	144 in 1 BOX	06/18/2016	
6		142 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:70766-001-07	1000 in 1 BOX	06/18/2016	
7		7 g in 1 BAG; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	03/01/2016	

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

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Yangzhou SION Commodity Co.,Ltd		546806042	manufacture(70766-001)

