

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

Amerfresh Fluoride Toothpaste

Active ingredients

Sodium monofluorophosphate 0.22%(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 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,water,sorbitol,hydrated silica,sodium lauryl sulfate,sodium carboxymethyl cellulose,flavor,sodium saccharine, polymethylene glycol, guar gum,methylisothiazolinone.
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

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22 g in 100 g

Inactive Ingredients

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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-003-01	144 in 1 BOX	05/25/2016	
1		17 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70766-003-02	144 in 1 BOX	05/25/2016	
2		24 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70766-003-03	144 in 1 BOX	05/25/2016	
3		43 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:70766-003-04	144 in 1 BOX	05/25/2016	
4		78 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:70766-003-05	144 in 1 BOX	06/18/2016	
5		85 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:70766-003-06	144 in 1 BOX	06/18/2016	
6		142 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:70766-003-07	1000 in 1 BOX	06/18/2016	
7		7 g in 1 BAG; Type 0: Not a Combination Product		
8	NDC:70766-003-10	1000 in 1 BOX	06/18/2016	
8		7.1 g in 1 BAG; Type 0: Not a Combination Product		
9	NDC:70766-003-08	5 in 1 CARTON	11/23/2016	
9		144 in 1 BOX		
9		17 g in 1 TUBE; Type 0: Not a Combination Product		
10	NDC:70766-003-09	5 in 1 CARTON	11/23/2016	
10		144 in 1 BOX		
10		24 g in 1 TUBE; Type 0: Not a Combination Product		
11	NDC:70766-003-11	72 in 1 BOX	06/18/2016	
11		142 g in 1 TUBE; Type 0: Not a Combination Product		
12	NDC:70766-003-12	72 in 1 BOX	06/18/2016	

12		181 g in 1 TUBE; Type 0: Not a Combination Product	
13	NDC:70766-003-13	4 in 1 CARTON	12/18/2017
13		125 in 1 BOX	
13		5 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	03/01/2016	

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(70766-003)

Revised: 12/2023

Yangzhou SION Commodity Co.,Ltd