

AMERFRESH TOOTH- sodium fluoride powder
Yangzhou SION Commodity Co.,Ltd

Amerfresh Fluoride Toothpaste

Active ingredients

Sodium Fluoride 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

For Use:

- Wet toothbrush and dip into powder until brush is fully covered
- 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, silica,sodium lauryl sulfate, flavor, sodium sacharine, methylisothiazolinone

Drug Facts		Drug Facts(continued)	
Active ingredient Sodium Fluoride 0.22% (0.1% w/v fluoride ion)..... Anticavity toothpaste	Purpose	<ul style="list-style-type: none"> • 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 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.			
Directions For Use • wet toothbrush and dip into powder until brush is fully covered • brush teeth and gurn line for at least 30 seconds,rinse and spit out thoroughly ▶		Inactive ingredients calcium carbonate,sodium saccharin,silica, sodium lauryl sulphate, flavor,methylisothiazolinone.	

Exclusive Distributor:AMERCARE Products Inc., Woodinville., WA 98072.
 Made in China.
 Code No.:GUJ/GC/565
 Batch No.:03
 Mfg.Date: 02/2018
 Exp Date: 01/2021



AMERFRESH®

FLUORIDE TOOTHPOWDER

NET WT. 1LB(454g)

AMERFRESH TOOTH			
sodium fluoride powder			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-004
Route of Administration	DENTAL		
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
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-004-01	40 in 1 CARTON	04/20/2018	
1		454 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:70766-004-02	4 in 1 CARTON	04/20/2018	
2		50 in 1 BOX		
2		57 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	04/20/2018	

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(70766-004)

Revised: 12/2024

Yangzhou SION Commodity Co.,Ltd