

AMERFRESH TOOTH- sodium fluoride powder
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.

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 saccharine, 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 gum 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 not final	part356	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: 3/2023

Yangzhou SION Commodity Co.,Ltd