

AMERFRESH TOOTHPOWDER- sodium fluoride powder
Yangzhou ONE & ONLY Personal Care Products Co., LTD

85162-007, Amerfresh Fluoride Toothpowder

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 under 6 years of age.

Directions

For Use:

- Wet toothbrush and dip into powder until brush is fully covered.
- Brush teeth and gum line for least 30 seconds, rinse and spit out thoroughly
- 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

AMERFRESH®

FLUORIDE TOOTHPOWDER

Net Wt. 1 LB (454g)

AMERFRESH
 FLUORIDE TOOTH
 Net Wt. 1 LB (45)

Drug Facts		Drug Facts(continued)
Active ingredient Sodium Fluoride 0.22% (0.1% w/v fluoride ion)..... Anticavity toothpaste	Purpose Aids in the prevention of dental cavities	<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.		Inactive ingredients: calcium carbonate,silica,sodium saccharin,sodium lauryl sulfate,flavor,methylisothiazolinone
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		

Exclusive Distributor:AMERCARE Products Inc., Woodinville., WA 98072.
 Made in China.
 Code No: GU100/565

AMERFRESH TOOTHPOWDER

sodium fluoride powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85162-007
Route of Administration	TOPICAL		

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
CALCIUM CARBONATE (UNII: H0G9379FGK)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85162-007-01	40 in 1 CARTON	08/13/2025	
1		454 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:85162-007-02	4 in 1 CARTON	08/13/2025	
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	08/13/2025	

Labeler - Yangzhou ONE & ONLY Personal Care Products Co., LTD (458091296)

Registrant - Yangzhou ONE & ONLY Personal Care Products Co., LTD (458091296)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou ONE & ONLY Personal Care Products Co., LTD		458091296	manufacture(85162-007)

Revised: 8/2025

Yangzhou ONE & ONLY Personal Care Products Co., LTD