

AMERFRESH FLUORIDE GEL- sodium fluoride paste, dentifrice
Yangzhou ONE & ONLY Personal Care Products Co., LTD

85162-001

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.

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

Sorbitol, Hydrated Silica, Water, PEG-8, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Saccharin, Glycerin, anthan Gum, Sodium Benzoate, Cetylpyridinium Chloride.

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AMER[®]FRESH

FLUORIDE *Gel* TOOTHPASTE NET WT. 3 OZ (85g)

Drug Facts		Drug Facts(continued)
Active ingredient Sodium Fluoride 0.22% (0.1% w/v fluoride ion)..... Anticavity toothpaste	Purpose	• 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. Inactive ingredients sorbitol, hydrated silica ,water, PEG-8,sodium lauryl sulfate,cellulose gum,flavor,sodium saccharin,glycerin,xanthan gum,sodium benzoate, cetylpyridinium chloride
	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 • 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 FLUORIDE GEL

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85162-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85162-001-01	144 in 1 BOX	01/16/2025	
1		17 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:85162-001-02	144 in 1 BOX	01/16/2025	
2		24 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:85162-001-03	144 in 1 BOX	01/16/2025	
3		43 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:85162-001-04	144 in 1 BOX	01/16/2025	

4		78 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:85162-001-05	144 in 1 BOX	01/16/2025	
5		85 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:85162-001-06	144 in 1 BOX	01/16/2025	
6		142 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:85162-001-07	1000 in 1 BOX	01/16/2025	
7		7 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	01/16/2025	

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(85162-001)

Revised: 1/2025

Yangzhou ONE & ONLY Personal Care Products Co., LTD