

**AMERFRESH- sodium fluoride paste  
SUHAN AEROSOL**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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**AMERFRESH FLUORIDE TOOTHPASTE**

**Active Ingredients**

Sodium fluoride-0.22%

**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 right away.

**Directions**

- 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.
- Do not swallow.
- To minimize the swallowing ,use a pea-sized amount in children under 6 years old.
- Supervise children's brushing until good habits are established.
- Children under 2 yrs : ask a dentist before use

**Inactive Ingredients**

Calcium Carbonate, Water,Sorbitol,Hydrated Silica, Sodium Lauryl Sulphate,Sodium Carboxymethyl cellulose, Flavor, Sodium Saccharin, Sodium methyl paraben, Sodium propyl paraben.

**Product label**

# AMERFRESH®

**FLUORIDE TOOTHPASTE NET WT. 0.25oz (7.1g)**

Drug Facts		Drug Facts (continued)
<b>Active ingredient</b> Sodium fluoride (0.1% w/v fluoride ion).....	<b>Purpose</b> 0.22% Anticavity toothpaste	<b>Directions</b> <ul style="list-style-type: none"> <li>• 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</li> <li>• do not swallow</li> <li>• To minimize swallowing, use a pea-sized amount in children under 6 years old</li> <li>• Supervise children's brushing until good habits are established</li> <li>• Children under 2 yrs: ask a dentist before use</li> </ul>
<b>Use</b> aids in the prevention of dental cavities		
<b>Warnings</b> Keep out of 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 right away		
		<b>Inactive ingredients</b> calcium carbonate, water, sorbitol, hydrated silica, sodium lauryl sulfate, sodium carboxymethyl cellulose, flavor, sodium saccharin, sodium methyl paraben, sodium propyl paraben.

Exclusive Distributor: AMERCARE Products Inc., Woodinville, WA 98072.

Made in India. Mfg. Lic. No.: MH/COB/32/KDVC-450, Mfg. Date & Batch No. on Crimp. Exp. Date: 3 years from date of Mfg.

sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:73398-114
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.2 mg in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73398-114-01	7.1 g in 1 POUCH; Type 0: Not a Combination Product	12/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/2020	

**Labeler** - SUHAN AEROSOL (861140760)

### Establishment

Name	Address	ID/FEI	Business Operations
SUHAN AEROSOL		861140760	manufacture(73398-114)

Revised: 12/2020

SUHAN AEROSOL