

**AMERFRESH FLUORIDE- sodium fluoride paste**  
**Amercare Products, Inc.**

*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**

**Drug Facts**

**Active Ingredient**

Sodium Fluoride 0.22% (0.1% w/v fluoride ion)

**Purpose**

Anticavity toothpaste

**Use**

aids prevention of dental cavities

**Warnings**

**Keep out of reach of children under 6 yrs. 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 2 yrs. and older: Brush teeth thoroughly after meals or at least twice a day or as directed by a dentist.
- Do not swallow
- To minimize 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**

sorbitol, water, hydrated silica, sodium lauryl sulfate, sodium carboxymethyl cellulose, flavor, sodium saccharine, sodium methyl paraben, sodium propyl paraben.

**Package Labeling:**

# AMERFRESH<sup>®</sup>

FLUORIDE TOOTHPASTE NET WT. 0.25 oz (7.1g)

Drug Facts	Drug Facts(continued)
<b>Active ingredient</b> <b>Purpose</b> Sodium Fluoride 0.22% (0.1% w/v fluoride ion)..... Anticavity toothpaste	<b>Directions</b> <ul style="list-style-type: none"><li>• Adults and children 2 yrs. and older: Brush teeth thoroughly after meals 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> <b>Keep out of reach of children under 6 yrs. of age</b> If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	<b>Inactive ingredients</b> sorbitol, water, hydrated silica, sodium lauryl sulfate, sodium carboxymethyl cellulose, flavor, sodium saccharine, sodium methyl paraben, sodium propyl paraben.

Exclusive Distributor:AMERCARE Products Inc., Woodinville.,WA 98072.  
Made in China. Mfg.Date on Bag.Exp.Date:3 years from date of Mfg.

AMERFRESH FLUORIDE

sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51460-3030
<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>
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51460-3030-1	7.1 g in 1 PACKET; Type 0: Not a Combination Product	10/12/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/12/2016	

**Labeler** - Amercare Products, Inc. (879289254)

Revised: 10/2016

Amercare Products, Inc.