

**AMERFRESH FLUORIDE- sodium monofluorophosphate 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.*

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**AmerFresh Fluoride Gel Toothpaste**

**Active Ingredient**

Sodium Monofluorophosphate 0.76%

**Purpose**

Anticavity toothpaste

**Use**

Aids in the prevention of dental cavities

**Warnings**

If more than used for brushing is accidentally swallowed, get medical help or contact a poison control center

Keep out of reach of children under 6 yrs. of age

**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**

SODIUM MONOFLUOROPHOSPHATE, CALCIUM CARBONATE, ANHYDROUS DIBASIC CALCIUM PHOSPHATE, CARBOXYMETHYLCELLULOSE, GLYCERIN, ALUMINUM HYDROXIDE, HYDRATED SILICA, POTASSIUM SORBATE, SODIUM LAURYL SULFATE, SORBITAN MONOOLEATE, SORBITOL, TITANIUM DIOXIDE, WATER, XANTHAN GUM.

**AmerFresh Fluoride Gel Toothpaste**

2  
2\*8  
1

# AMERFRESH<sup>®</sup>

**FLUORIDE Gel TOOTHPASTE    NET WT. 0.6oz (17g)**

13  
  
3\*8  
3

**Drug Facts**

<b>Active ingredient</b> Sodium monofluorophosphate 0.76%.....	<b>Purpose</b> Anticavity toothpaste
<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.	

**Drug Facts(continued)**

**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** calcium carbonate, calcium hydrogen phosphate, carboxymethyl cellulose, flavor, glycerin, hydrated alumina, hydrated silica, potassium sorbate, saccharine sodium, sodium lauryl sulfate, sorbitan monooleate, sorbitol, titanium dioxide, water, xanthan gum.

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.

4.5

<b>AMERFRESH FLUORIDE</b>			
sodium monofluorophosphate paste			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51460-3002
<b>Route of Administration</b>	DENTAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII: Q80VPU408O)	FLUORIDE ION	0.76 g in 1 g	
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>	<b>Strength</b>		
CALCIUM CARBONATE (UNII: H0G9379FGK)			
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)			
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)			

GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51460-3002-1	17 g in 1 TUBE; Type 0: Not a Combination Product	09/12/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/12/2016	

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

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