# 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 GelToothpaste

# **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 accidently swallowed, get medical help or contact a poison control center

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

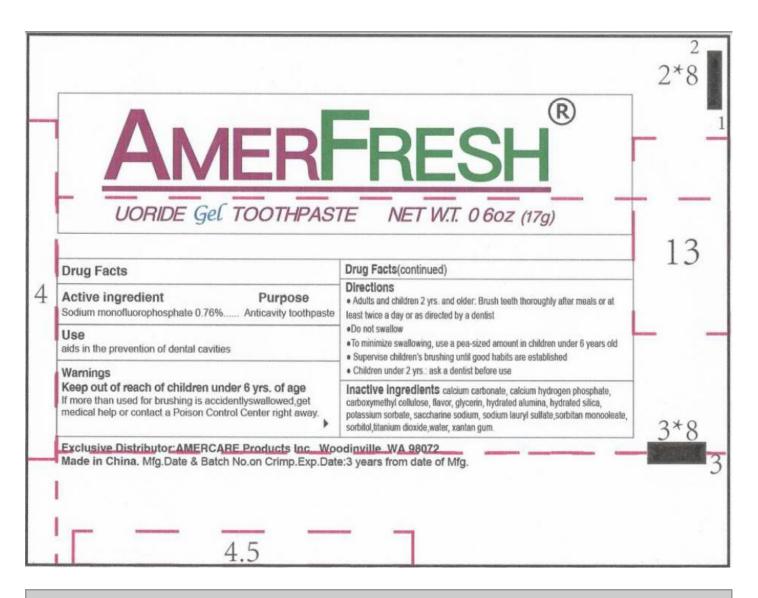
#### **Directions**

- Adults and children 2 yrs. and older: Brush teeth throughtly 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



#### AMERFRESH FLUORIDE

sodium monofluorophosphate paste

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:51460-3002

Route of Administration DENTAL

#### Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
SO DIUM MO NO FLUO RO PHO SPHA UNII:Q80 VPU408O)	TE (UNII: C810JCZ56Q) (FLUORIDE ION -	FLUORIDE ION	0.76 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)	
CARBO XYMETHYLCELLULO SE (UNII: 05JZI7B19X)	

GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITAN MONO OLEATE (UNII: 06 XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

ı	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)

Revised: 9/2016 Amercare Products, Inc.