

**AMERFRESH- sodium monofluorophosphate paste, dentifrice**  
**Amercure 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 Toothpaste**

**Drug Facts**

**Active ingredient**

Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion)

**Purpose**

Anticavity toothpaste

**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
- 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**

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

**Exclusive Distributor: AMERCARE Products Inc., Seattle, WA 98165-2226.**

**PRINCIPAL DISPLAY PANEL - 85 g Tube Label - NDC 51460-1112**

**AMERFRESH®**

***FLUORIDE TOOTHPASTE NET WT. 3 oz (85g)***

# AMERFRESH®

**FLUORIDE TOOTHPASTE NET WT. 3 oz (85g)**

Drug Facts		Drug Facts (continued)
<b>Active ingredient</b> Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion).....	<b>Purpose</b> Anticavity toothpaste	<ul style="list-style-type: none"> <li>• Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing).</li> <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 or a doctor.</li> <li>• Children under 6 years of age: Do not use unless directed by a doctor or dentist</li> </ul>
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**Made in India.** Code No.: GUJ/GC/565 Mfg. Date & Batch No. on Crimp. Exp. Date: 3 years from date of Mfg.

**PRINCIPAL DISPLAY PANEL - 85 g Tube Label - NDC 51460-1114**

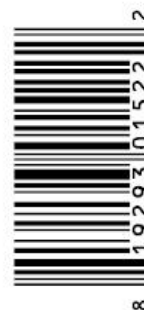
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## AMERFRESH

sodium monofluorophosphate paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51460-1112
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
Calcium Carbonate (UNII: H0G9379FGK)	
Water (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Carboxymethylcellulose Sodium (UNII: K679OBS311)	
Saccharin Sodium (UNII: SB8ZUX40TY)	

<b>Methylparaben Sodium</b> (UNII: CR6K9C2NHK)				
<b>Propylparaben Sodium</b> (UNII: 625NNB0G9N)				
<b>Product Characteristics</b>				
<b>Color</b>	WHITE	<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	MINT	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51460-1112-1	85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51460-1112-2	7.1 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:51460-1112-3	1 in 1 BOX		
3		85 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:51460-1112-4	17 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:51460-1112-5	24 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:51460-1112-6	43 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:51460-1112-7	1 in 1 BOX		
7		43 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:51460-1112-8	130 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:51460-1112-9	181 g in 1 TUBE; Type 0: Not a Combination Product		
10	NDC:51460-1112-0	142 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part355	11/14/2012		

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OTC MONOGRAPH FINAL	part355	11/14/2012	

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

Revised: 1/2015

Amercare Products, Inc.