

**AMERFRESH- sodium monofluorophosphate paste, dentifrice**  
**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 TOOTHPASTE*

**DRUG FACTS**

**Active ingredient**

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

**Purpose**

Anticavity

**Use**

helps protect against 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 centre immediately.

**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 or a physician.
Children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.
Children under 2 years	Ask a dentist or physician.

**Inactive Ingredients**

Sorbitol, Silica, Calcium Carbonate, Methyl Paraben Sodium, Propyl Paraben Sodium, Flavour, Sodium Saccharin, Treated water, SCMC, Sodium Lauryl Sulfate.

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

**PRINCIPAL DISPLAY PANEL - 141 g Carton Label**

**AMERFRESH®**

*FLUORIDE TOOTHPASTE*

NET WT. 5 oz (141g)

# AMERFRESH®

FLUORIDE TOOTHPASTE NET WT. 5 oz (141g)

DRUG FACTS		DRUG FACTS (continued)	
<b>Active ingredient :</b> Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion).....	<b>Purpose</b> Anticavity	<b>Directions:</b> 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 physician.
<b>Use:</b> helps protect against cavities.		Children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.
<b>Warning :</b> 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 centre immediately.		Children under 2 years	Ask a dentist or physician.
<b>Inactive Ingredients :</b> Sorbitol, Silica, Calcium Carbonate, Methyl Paraben Sodium, Propyl Paraben Sodium, Flavour, Sodium Saccharin, Treated water, SMC, Sodium Lauryl Sulfate.			



Exclusive Distributor: AMERCARE Products Inc. Seattle, WA 98165-2226. Made in India. N.C.No. DD/COS/DD/C/340 Mfg. Date & Batch no. on Crimp Exp. date: 3 years from date of Mfg.

## AMERFRESH

sodium monofluorophosphate paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51460-5000
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Sodium Monofluorophosphate</b> (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Mono fluorophosphate	0.76 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Calcium Carbonate</b> (UNII: H0G9379FGK)	42 g in 100 g
<b>Water</b> (UNII: 059QF0K00R)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Sodium Lauryl Sulfate</b> (UNII: 368GB5141J)	
<b>Carboxymethylcellulose Sodium</b> (UNII: K679OBS311)	
<b>Saccharin Sodium</b> (UNII: SB8ZUX40TY)	
<b>Methylparaben Sodium</b> (UNII: CR6K9C2NHK)	

**Propylparaben Sodium** (UNII: 625NNB0G9N)

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	score with uneven pieces
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51460-5000-1	141 g in 1 TUBE		
2	NDC:51460-5000-2	85 g in 1 TUBE		
3	NDC:51460-5000-3	42 g in 1 TUBE		
4	NDC:51460-5000-4	24 g in 1 TUBE		
5	NDC:51460-5000-5	17 g in 1 TUBE		
6	NDC:51460-5000-6	4.24 g in 1 POUCH		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	01/01/1996	

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

Revised: 3/2011

Amercare Products Inc