

AMERFRESH- sodium fluoride gel, 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.

AmerFresh®
Fluoride Gel Toothpaste

Drug Facts

Active ingredient

Sodium Fluoride 0.22% (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 2 years of age: Consult a dentist or doctor

Inactive ingredients

sorbitol, water, 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 - 85g Tube Label

AMERFRESH®

FLUORIDE Gel TOOTHPASTE

NET WT. 3 oz (85g)

AMERFRESH®

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

Drug Facts		Drug Facts (continued)
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Made in India. Code No.: GUJ/GC/565 Mfg. Dt. & B. No. on Crimp. Exp. dt: 3 yrs from date of Mfg.

AMERFRESH

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51460-1111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	0.187 g in 85 g

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0K00R)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Carboxymethylcellulose Sodium (UNII: K679OBS311)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Methylparaben Sodium (UNII: CR6K9C2NHK)	
Propylparaben Sodium (UNII: 625NNB0G9N)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51460-1111-1	85 g in 1 TUBE		
2	NDC:51460-1111-2	7.1 g in 1 PACKET		
3	NDC:51460-1111-3	17 g in 1 TUBE		
4	NDC:51460-1111-4	24 g in 1 TUBE		
5	NDC:51460-1111-5	43 g in 1 TUBE		
6	NDC:51460-1111-6	130 g in 1 TUBE		
7	NDC:51460-1111-7	181 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	11/14/2012	

Labeler - Amercare Products, Inc. (879289254)

Revised: 11/2012

Amercare Products, Inc.