

AMERFRESH CLEAR- sodium fluoride 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.

AMERFRESH®

FLUORIDE gel TOOTHPASTE

DRUG FACTS

Active ingredient

Sodium Fluoride 0.22% (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 Ingredient

Sorbitol, Silica, 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 - 181 g Carton Label

AMERFRESH®

FLUORIDE gel TOOTHPASTE

NET WT. 6.4 oz (181g)

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DRUG FACTS		DRUG FACTS (continued)	
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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 CLEAR

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51460-5010
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	0.22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	64 g in 100 g
Water (UNII: 059QF0KO0R)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
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	score with uneven pieces
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51460-5010-1	85 g in 1 TUBE		
2	NDC:51460-5010-2	42 g in 1 TUBE		
3	NDC:51460-5010-3	24 g in 1 TUBE		
4	NDC:51460-5010-4	17 g in 1 TUBE		
5	NDC:51460-5010-5	181 g in 1 TUBE		

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