

AMERFRESH- sodium monofluorophosphate powder, 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 Toothpowder

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

For Use

- wet toothbrush and dip into powder until brush is fully covered
- brush teeth and gum line for at least 30 seconds, rinse and spit out thoroughly
- 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, sodium carboxymethyl cellulose, sodium saccharin, sodium lauryl sulfate, flavour, silica, sodium methyl paraben, sodium propyl paraben, CI 16255 Q.S.

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

PRINCIPAL DISPLAY PANEL - 57 g Packet Label

AMERFRESH®
FLUORIDE TOOTHPOWDER

NET WT. 2 oz (57g)

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Made in India. Code No.: GUJ/GC/565

Batch No.:

Mfg. Date:

Exp. Date:

AMERFRESH[®]
FLUORIDE TOOTHPOWDER

NET WT. 2 oz (57g)

AMERFRESH

sodium monofluorophosphate powder, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51460-1113
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.4332 g in 57 g

Inactive Ingredients

Ingredient Name	Strength
calcium carbonate (UNII: H0G9379FGK)	
carboxymethylcellulose sodium (UNII: K679OBS311)	
saccharin sodium (UNII: SB8ZUX40TY)	
sodium lauryl sulfate (UNII: 368GB5141J)	

hydrated silica (UNII: Y6O7T4G8P9)	
methylparaben sodium (UNII: CR6K9C2NHK)	
propylparaben sodium (UNII: 625NNB0G9N)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51460-1113-1	57 g in 1 PACKET		
2	NDC:51460-1113-2	446 g in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/20/2011	

Labeler - Amercare Products, Inc. (879289254)

Revised: 1/2013

Amercare Products, Inc.