

AMERFRESH- sodium monofluorophosphate powder
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 TOOTHPOWDER

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 center 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

Calcium Carbonate, Sodium Carboxy Methyl Cellulose, Sodium Saccharin, Sodium Lauryl Sulfate, Flavour, Silica, Methyl Paraben Sodium, Propyl Paraben Sodium and Cl 16255 Q.S.

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

PRINCIPAL DISPLAY PANEL - 446 g Carton

AMERFRESH®
FLUORIDE TOOTHPOWDER

NET WEIGHT 1 lb (446 g)

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DRUG FACTS		DRUG FACTS (continued)	
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Use: 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.
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sodium monofluorophosphate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51460-0502
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (fluoride ion - UNII:Q80VPU408O)	Sodium Monofluorophosphate	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Calcium Carbonate (UNII: H0G9379FGK)	94.98 g in 100 g
Carboxymethylcellulose Sodium (UNII: K679OBS311)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Methylparaben Sodium (UNII: CR6K9C2NHK)	
Propylparaben Sodium (UNII: 625NNB0G9N)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Ponceau 4R (UNII: Z525CBK9PG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51460-0502-1	446 g in 1 POUCH		
2	NDC:51460-0502-2	57 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 - Amcare Products Inc (879289254)

