

ADVANCED WHITENING ANTICAVITY FLUORIDE - sodium monofluorophosphate paste, dentifrice

Personal Care Products, LLC

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.

ADVANCED WHITENING ANTICAVITY FLUORIDE

Active Ingredient

Sodium Monofluorophosphate 0.76%

Purpose

Anticavity toothpaste

Use

Aids in the prevention of cavities

If more than is used for brushing is accidentally swallowed get medical help or contact a poison control center right away.

Keep out of reach of children under 6 yrs of age.

Directions

adults and children 2 years. and older: brush teeth thoroughly after meals or at least twice a day or as directed by a dentist.

do not swallow

to minimize swallowing, use a pea-sized amount in children under 6 years old

supervise children's brushing until good habits are established

children under 2y ears: ask a dentist before use.

Inactive ingredients-

calcium carbonate, calcium hydrogen phosphate, carboxymethyl cellulose, flavor, glycerin, hydrated alumina, hydrated silica, potassium sorbate, saccharin sodium, sodium lauryl sulfate, sorbitan monooleate, sorbitol, titanium dioxide, water, xanthan gum.

Distributed by:

Personal Care Products, LLC

Bingham Farms, MI 48025-2463

Made in China

Advanced Whitening Anticavity Fluoride Toothpaste

Net Wt 6.4oz (181g)

Fresh Mint

Fights Tarter Build-up



Advanced Whitening Anticavity Fluoride Toothpaste	Drug Facts		Drug Facts (continued)	 Distributed by: Personal Care Products, LLC Bingham Farms, MI 48025-2463 Made in China
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	Use aids in the prevention of cavities		Inactive ingredients calcium carbonate, calcium hydrogen phosphate, carboxymethyl cellulose, flavor, glycerin, hydrated alumina, hydrated silica, potassium sorbate, saccharin sodium, sodium lauryl sulfate, sorbitan monooleate, sorbitol, titanium dioxide, water, xanthan gum.	
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sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-2238
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)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-2238-6	1 in 1 BOX		
1		181 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/24/2011	

Labeler - Personal Care Products, LLC (966155082)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Lierkang Daily Used Chemicals Co Ltd		531075083	manufacture

Revised: 12/2011

Personal Care Products, LLC