ADVANCED FLUORIDE ANTICAVITY- 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 FLUORIDE ANTICAVITY TOOTHPASTE - 9181

Active Ingredient Drug Facts

Sodium Monofluorophosphate 0.76%

Purpose

Anticavity toothpaste

Use

Aids in the prevention of cavities

Warnings

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

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.

ADVANCED FLUORIDE ANTICAVITY product label

CAVITY FIGHTING TOOTHPASTE

Distributed by:

Personal Care Products, LLC

Bingham Farms, MI 48025-2463

Made in China

Advanced Fluoride Anticavity Toothpaste

New Ultra Breath Freshener Stripe

Net Wt 6.4oz (181g)

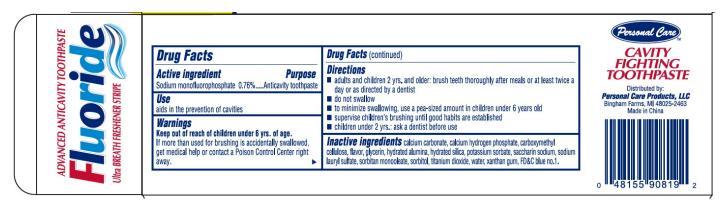
Multi

Protection

Fights Cavities

Freshens Breath







ADVANCED FLUORIDE ANTICAVITY

sodium monofluorophosphate paste, dentifrice

Product Information

1 Todact Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-9181

Route of Administration DENTAL

l	Active Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength
	SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1000 mg in 181 g

Inactive Ingredients	
Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

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WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:29500-9181-6	1 in 1 PACKAGE	07/24/2017	
1	181 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/24/2017	

Labeler - Personal Care Products, LLC (966155082)

Registrant - Personal Care Products, LLC (966155082)

Revised: 8/2017 Personal Care Products, LLC