

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash
Publix Super Markets, Inc

Anticavity Fluoride Mouthwash
163.005/163AF/AG

Active ingredient

Sodium fluoride 0.0221% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and older:

- use twice daily after brushing your teeth with toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- supervise children as necessary until capable of using without supervision
- children under 12 years of age: consult a dentist or doctor

Other information

- store at controlled room temperature 20° -25° C (68° - 77° F)
- cold weather may temporarily cloud this product

Inactive ingredients

water, alcohol (21.6 %v/v), sorbitol, poloxamer 407, eucalyptol, flavor, methyl salicylate, menthol, phosphoric acid, sodium saccharin, thymol, disodium phosphate, sucralose, red 40, blue 1

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine Total Care Anticavity Mouthwash.

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.,
3300 PUBLIX CORPORATE PARKWAY
LAKELAND, FL 33811 publix.com

principal display panel

Publix

EUCALYPTUS MINT

anticavity

FLUORIDE MOUTHWASH

Sodium Fluoride and Acidulated Phosphate Topical Solution

- Helps prevent cavities
- Restores enamel
- Helps strengthen teeth
- Helps kill germs that cause bad breath

Compare to the active ingredient in Listerine Total Care Anticavity Mouthwash*

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

IMPORTANT: READ DIRECTIONS FOR PROPER USE.

1 L (33.8 FL OZ)

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L0011421FA

ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-163
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
EUCALYPTOL (UNII: RV6J6604TK)	

METHYL SALICYLATE (UNII: LAV5U5022Y)	
menthol (UNII: L7T10EIP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
THYMOL (UNII: 3J50XA376E)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
sucralose (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-163-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/20/2011	

Labeler - Publix Super Markets, Inc (006922009)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(56062-163)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(56062-163)