ANTICAVITY- sodium fluoride mouthwash PUBLIX SUPER MARKETS, 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.

Glowing White Anticavity Mouthrinse 435.000-435AA

Active Ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities

Warnings

for this product

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 6 years of age and older:

- use twice a day after brushing your teeth with a 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
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision
- children under 6 years of age: consult a dentist or doctor

Other information

• store at room temperature (59º-77ºF)

Inactive ingredients

water, alcohol (8%), hydrogen peroxide, poloxamer 407, sodium saccharin, sucralose, menthol, phosphoric acid, disodium phosphate, flavor

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine HealthyWhite Vibrant Anticavity Mouthrinse

Contains peroxide, which releases oxygen while whitening. This may cause the bottle to inflate slightly or release air when opened.

Distributed by: Publix Super Markets, Inc.,

3300 Publix Corporate Parkway

Lakeland, FL 33811 publix.com

PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

Principal Display Panel

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Antivavity

Glowing white

Mouthrinse

- Begins working on contact
- 5 days to whiter teeth
- Helps strengthen teeth
- Kills germs that cause bad breath

*Compare to the ingredients of Listerine Healthywhite Vibrant Anticavity Mouthrinse Sealed with printed neckband for your protection

IMPORTANT: Read directions for proper use.

32 FL OZ (1 QT) 946 mL





- Begins working on contact
- . 5 days to whiter teeth
- Helps strengthen teeth
- Kills germs that cause bad breath

*Compare to the active ingredient of Listerine® HealthyWhite™ Vibrant Anticavity Fluoride Mouthrinse

> Sealed With Printed Neckband For Your Protection IMPORTANT: read directions for proper use.

32 FL OZ (1 QT) 946 mL

L0015085FB

ANTICAVITY

sodium fluoride mouthwash

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Prod	LICT	Inform	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:56062-435

Route of Administration oral

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION 0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MENTHOL (UNII: L7T10EIP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062- 435-45	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2015	
2	NDC:56062- 435-43	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/15/2015	

Labeler - PUBLIX SUPER MARKETS, INC (006922009)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(56062-435)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(56062-435)

Revised: 2/2023 PUBLIX SUPER MARKETS, INC