

ANTICAVITY- sodium fluoride mouthwash

Kroger Co

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.

drug facts

Active Ingredient

Sodium fluoride 0.02% (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 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

Inactive ingredients

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

Other information

- store at room temperature (59°-77°F)

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

*Listerine is a registered trademark of Johnson & Johnson Healthcare Products, New Brunswick, NJ 08903. Johnson & Johnson Healthcare Products is not affiliated with The Kroger Co. or this product.

DISTRIBUTED BY

The Kroger Co.

Cincinnati, OH 45202

800-632-6900 www.kroger.com

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

Compare to the ingredients of Listerine Healthy White Vibrant Anticavity Mouthrinse *See back label

Fresh Mint

Whitening Anticavity Mouthrinse

Safely whitens teeth

Kills germs that cause bad breath

Helps strengthen teeth

Sealed with printed neckband for your protection

IMPORTANT: Read directions for proper use

946 mL (32 FL OZ)

COMPARE to the ingredients of LISTERINE® HEALTHY WHITE
VIBRANT ANTICAVITY MOUTHRINSE *See Back Label



FROM OUR FAMILY
TO YOURS

Fresh Mint

WHITENING ANTICAVITY MOUTHRINSE

- Safely Whitens Teeth
- Kills Germs that Cause Bad Breath
- Helps Strengthen Teeth

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION
IMPORTANT: READ DIRECTIONS FOR PROPER USE.

32 FL OZ (1 QT) 946 mL

L0015081FA

ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-435
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 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: L7T10EP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-435-45	946 mL in 1 BOTTLE, PLASTIC; 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	09/15/2015	

Labeler - Kroger Co (006999528)

Registrant - Vi-Jon, Inc. (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc.		790752542	manufacture(30142-435)