

ANTICAVITY- sodium fluoride mouthwash
Libertu Procurement, 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.

Anticavity Rinse
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

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.

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

To open: remove tamper evident neckband. Squeeze both tabs at base of cap while turning the cap until loose. To close: Place cap back on bottle and turn cap until it clicks twice and feels secure

Distributed by

Liberty Procurement Co. Inc.

Union, NJ 07083 USA

www.facevalues.com

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Or Your Money Back

principal display panel

CORE VALUES

Compare to Listerine Healty White Vibrant

Advanced WHITENING ANTICAVITY MOUTHRINSE

- Begins working on contact
- Safely whitens teeth
- Kills germs that cause bad breath

5 DAYS to Whiter Teeth

Fresh Mint

IMPORTANT: Read directions for proper use.

946 mL (32 FL OZ)

Sealed With Printed Neckband For Your Protection

CORE VALUES™

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L0015075FC

ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-435
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: TUF21VW3M2)			
	SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
	SUCRALOSE (UNII: 96K6UQ3ZD4)			
	MENTHOL (UNII: L7T10EIP3A)			
	PHOSPHORIC ACID (UNII: E4GA8884NN)			
	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-435-45	946 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 - Libertu Procurement, Inc (804085293)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63940-435)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(63940-435)