

## **ANTICAVITY- sodium fluoride rinse**

### **Big Lots**

*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.*

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### **Anticavity Fluoride Rinse**

**971**

#### **Active Ingredient**

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

#### **Purpose**

Anticavity rinse

#### **Use**

aids in the prevention of dental cavities

#### **Warning**

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 immediately

#### **Directions**

Adults and children 6 years of age and older:

- use twice daily 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 20° - 25° C (68° - 77° F)
- cold weather may temporarily cloud this product

#### **Inactive ingredients**

water, sorbitol, propylene glycol, flavor, sodium lauryl sulfate, poloxamer 407, sodium benzoate, phosphoric acid, sodium saccharin, disodium phosphate, sucralose, red 40, blue 1

## **Questions?**

1-888-593-0593

Sealed With Printed Neckband For Your Protection

This product is not intended to replace brushing or flossing

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

Manufactured for Big Lots By Vi-Jon, Inc.

8515 Page Avenue

St. Louis, MO 63114

971.000/971AA

## **principal display panel**

SOUNDBODY

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

BURN FREE

Fluoride Anti-Cavity Mouthrinse

Sodium Fluoride and Acidulated Phosphate Topical Solution

Helps Strengthen Teeth to Fight Cavities

Helps Restore Enamel

Kill Bad Breath Germs

Freshens Breath

Cleans the Entire Mouth

Alcohol Free

**IMPORTANT:** read directions for proper use.

EUCALYPTUS MINT

1 L (33.8 FL OZ)



Compare to the active  
Ingredient in Listerine Total Care  
Zero Anticavity Mouthwash\*

**BURN FREE**

# Fluoride Anti-Cavity Mouthrinse

Sodium Fluoride and Acidulated Phosphate Topical Solution

- Helps Strengthen Teeth to Fight Cavities
- Helps Restore Enamel
- Kills Bad Breath Germs
- Freshens Breath
- Cleans the Entire Mouth\*\*
- Alcohol Free



IMPORTANT: read directions for proper use.

**EUCALYPTUS MINT**

1 L (33.8 FL OZ)

L0017524FA

## ANTICAVITY

sodium fluoride rinse

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-971
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
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:50594-971-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/19/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/19/2017	

**Labeler** - Big Lots (017885351)

**Registrant** - Vi-Jon (790752542)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(50594-971)