

**ANTICAVITY- sodium fluoride rinse**  
**Demoulas**

*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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**Market Basket 971.001-971AB**

**Active Ingredients**

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 right away

**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 controlled room temperature 20° - 25°C (68° - 77° F)

- cold weather may temporarily cloud this product

### **Inactive ingredients**

water, sorbitol, propylene glycol, poloxamer 407, sodium lauryl sulfate, flavor, sodium benzoate, phosphoric acid, eucalyptol, methyl salicylate, thymol, sodium saccharin, menthol, disodium phosphate, sucralose, Mentha viridis (spearmint) leaf oil, Mentha piperita (peppermint) oil, red 40, blue 1

### **Disclaimer**

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc. distributor of Listerine Total Care Zero Alcohol Anticavity Fresh Mint Mouthwash

### **Adverse reactions section**

DISTRIBUTED BY DEMOULAS SUPER MARKETS, INC.

875 East Street

Tewksbury, MA 01876

"MORE FOR YOUR DOLLAR"

MARKET BASKET

Compare to Listerine Total Care Zero Alcohol Mouthwash

FLOURIDE

ANTI-CAVITY MOUTHWASH

Sodium fluoride and Acidulated Phosphate Topical Solution

Fresh Mint

- Helps strengthen teeth to fight cavities
- Restores enamel
- Helps kill bad breath germs
- Alcohol Free

IMPORTANT: Read directions for proper use.

Sealed With Printed Neckband For our Protection

1L (33.8 FL OZ)

"MORE FOR YOUR DOLLAR"

**MARKET BASKET**

Compare to  
Listerine® Total Care  
Zero Alcohol Mouthwash\*

# FLUORIDE ANTI-CAVITY M O U T H W A S H

Sodium Fluoride and Acidulated  
Phosphate Topical Solution

## Fresh Mint

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- Restores enamel
- Helps kill bad breath germs
- Alcohol Free

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

Sealed With Printed Neckband For Your Protection

**1 L (33.8 FL OZ)**

L0020368FA

## ANTICAVITY

sodium fluoride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53942-971
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
EUCALYPTOL (UNII: RV6J6604TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
THYMOL (UNII: 3J50XA376E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SPEARMINT OIL (UNII: C3M81465G5)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
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:53942-971-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/04/2022	

**Labeler** - Demoulas (007869647)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(53942-971)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(53942-971)

