

ANTICAVITY- sodium fluoride mouthwash
Demoulas 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.

Anticavity Mouthwash
163.005/AF-AG

Active Ingredient

Sodium fluoride 0.02% w/v (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 12 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, alcohol (21.6 %v/v), sorbitol, poloxamer 407, eucalyptol, flavor, methyl salicylate, menthol, phosphoric acid, sodium saccharin, thymol, disodium phosphate, sucralose, red 40, blue 1

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

DISTRIBUTED BY

DEMOULAS SUPER MARKETS, INC

875 EAST STREET

TEWKSBURY, MA 01876

DSP-TN-15000 DSP-MO-34 SDS-TN-15012

principal panel display

"More for your dollar"

MARKET BASKET

Sealed With Printed Neckband For Your Protection

MARKET BASKET

Compare to Listerine Total Care Anticavity Mouthwash*

ANTICAVITY MOUTHWASH

Sodium Fluoride and Acidulated Phosphate Topical Solution

Eucalyptus Mint

- Helps prevent cavities
- Helps strengthen teeth
- Helps kill germs that cause bad breath
- Freshens breath
- Restores enamel

IMPORTANT: Read directions for proper use.

Sealed With Printed Neckband For Your Protection

1L (33.8 FL OZ)

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L0018994FA

ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53942-163
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
Eucalyptol (UNII: RV6J6604TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
menthol (UNII: L7T10EIP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
thymoI (UNII: 3J50XA376E)	
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:53942-163-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/13/2006	

Labeler - Demoulas Super Markets, Inc. (007869647)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(53942-163)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(53942-163)

