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.

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

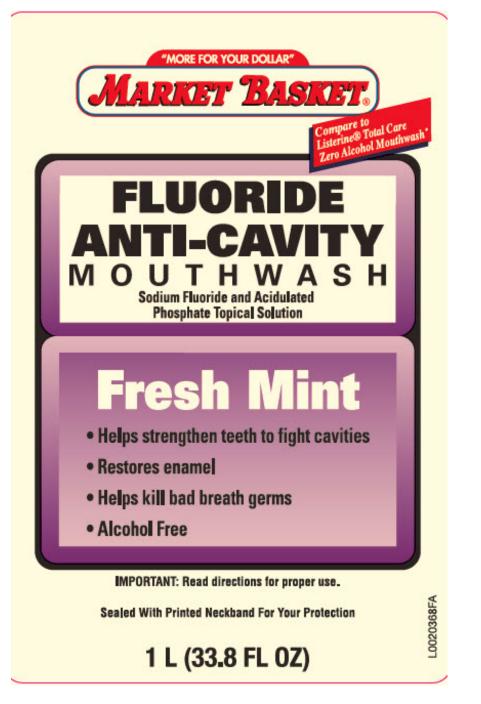
Fresh Mint

- 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)



ANTICAVITY						
sodium fluoride rinse						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC	:53942-971	
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Ingred		Basis of Streng	gth	Strength		
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)			FLUORIDE ION		0.02 mg in 1 mL	

Inactive Ingr	edients				
		Ingredient Name		Strength	
water (UNII: 059Q	F0KO0R)				
SORBITOL (UNII:	506T60A25R)				
PROPYLENE GLY	COL (UNII: 6DC9Q16	57V3)			
POLOXAMER 407	(UNII: TUF2IVW3M2)				
SODIUM LAURYL	SULFATE (UNII: 368	3GB5141J)			
SODIUM BENZO	TE (UNII: OJ245FE5	EU)			
PHOSPHORIC AC	ID (UNII: E4GA8884M	JN)			
EUCALYPTOL (UN	III: RV6J6604TK)				
METHYL SALICYI	ATE (UNII: LAV5U50	22Y)			
THYMOL (UNII: 3J	50XA376E)				
SACCHARIN SOD	IUM (UNII: SB8ZUX4	0TY)			
MENTHOL (UNII: I	.7T10EIP3A)				
SODIUM PHOSPH	IATE, DIBASIC, AN	HYDROUS (UNII: 22ADO53M6F)			
SUCRALOSE (UNI	: 96K6UQ3ZD4)				
	UNII: C3M81465G5)				
PEPPERMINT OIL	. (UNII: AV092KU4JH)				
FD&C RED NO. 4	0 (UNII: WZB9127XC)A)			
FD&C BLUE NO.	1 (UNII: H3R47K3TB)	0)			
Packaging					
# Item Code	Pacl	cage Description	Marketing Start Date	Marketing End Date	
1 NDC:53942- 971-86	1000 mL in 1 BOTT Combination Produ	LE, PLASTIC; Type 0: Not a ct	04/04/2022		
Marketing Information					
Marketing Category	Applicatio	n Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph f	nal 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			

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

Revised: 4/2022