

ANTICAVITY- sodium fluoride rinse
RETAIL BUSINESS SERVICES, LLC

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.

Burn-Free Fluoride Anti-Cavity Mouthwash
971.001/971AB

Sealed With Printed Neckband for Your Protection

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 daily after brushing your teeth with a toothpaste
- vigorously swish 10 mL 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

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

DISTRIBUTED BY ADUSA DISTRIBUTION, LLC

SALISBURY, NC 28147

For product questions and concerns,

contact us at 1-833-992-3872

Quality guaranteed or your money back.

Principal Panel Display

CAREONE

Compare to Listerine Total Care Zero Alcohol Anticavity Fresh Mint Mouthwash*

BURN FREE FLUORIDE

ANTI-CAVITY MOTHWASH

SODIUM FLUORIDE AND ACIDULATED

PHOSPHATE TOPICAL SOLUTION

HELPS STRENGTHEN TEETH TO FIGHT CAVITIES

HELPS RESTORE ENAMEL

FRESH MINT FLAVOR

IMPORTANT: read directions for proper use.

NET 33.8 FL OZ (1.05 QT) 1L

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L0020735FA

NET 33.8 FL OZ (1.05 QT) 1 L

ANTICAVITY

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-971
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.2 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:72476-971-86	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/08/2022	

Labeler - RETAIL BUSINESS SERVICES, LLC (967989935)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72476-971)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72476-971)

Revised: 4/2023

RETAIL BUSINESS SERVICES, LLC