

ANTICAVITY- sodium fluoride rinse
Rite Aid

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

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 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

**This product is not intended to replace brushing or flossing.

Distributed by:

Rite Aid 30 Hunter Lane,

Camp Hill, PA 17011

www.riteaid.com

SATISFACTION GUARANTEE

If you're not satisfied, we'll happily refund your money.

Principal Panel Display

Sealed with printed neckband for your protection

Do not use if band around cap is broken or missing.

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

FREE FROM

ALCOHOL FREE

Fluoride AntiCavity Mouthwash

Sodium Fluoride & Acidulated

Phosphate Topical Solution

Anticavity Fluoride Rinse

Fresh Mint

6 Benefits

Restores enamel

Kills bad breath germs

Helps strengthen teeth to fight cavities

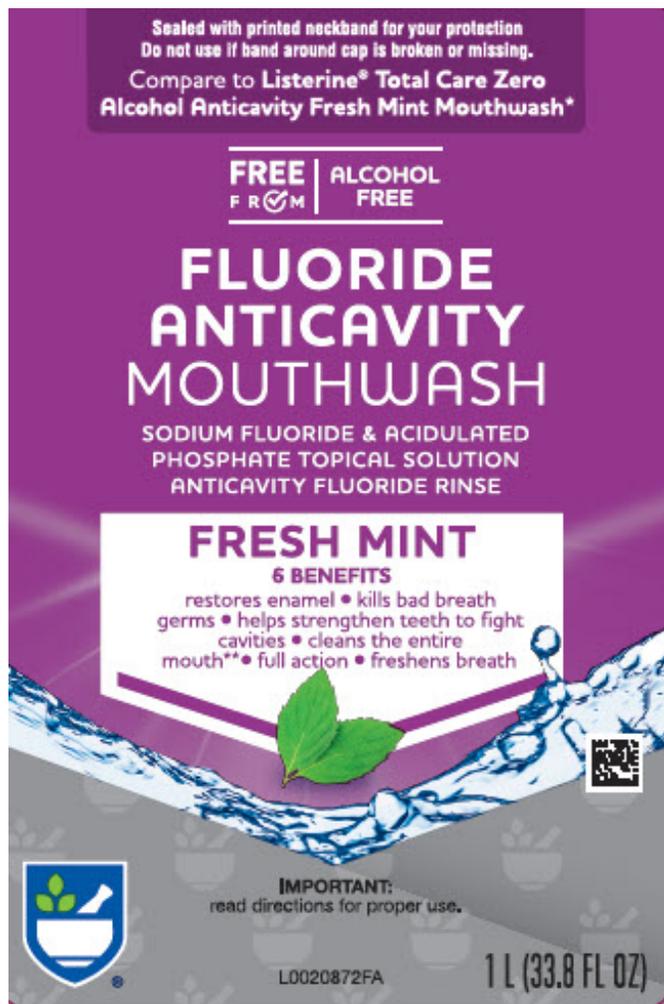
Cleans the entire mouth**

Full action

Freshens breath

Important: read directions for proper use.

1L (33.8 FL OZ)



ANTICAVITY

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-9718
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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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:11822-9718-6	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/05/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/05/2022	

Labeler - Rite Aid (014578892)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(11822-9718)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11822-9718)