# ANTICAVITY- sodium fluoride rinse CVS Pharmacy, 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.

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# **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 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:

CVS Pharmacy Inc.

One CVS Drive

Woonsocket, RI 02895

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CVS.com

1-800-SHOP CVS

CVS Quality money back guarantee

## Principal display panel

CVS Health

Compare to Listerine Total Care Zero Anticavity Mouthwash\*

Alcohol Free

Anticavity Fluoride

Mouthwash

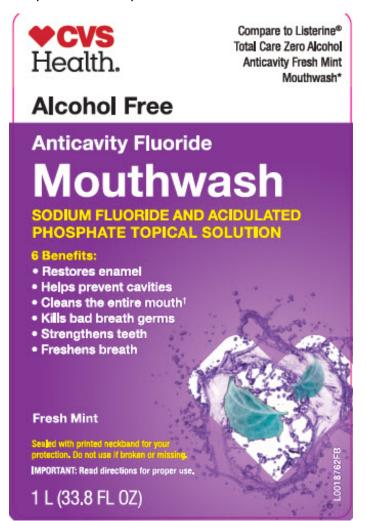
SODIUM FLUORIDE AND ACIDULATED PHOSPHATE TOPCAL SOLUTION

#### 6 Benefits:

- Restores enamel
- Helps prevent cavities
- Cleans the entire mouth
- Kills bad breath germs
- Strengthens teeth
- Freshens breath
- Fresh mint

Sealed with printed neckband for your protection. Do not use if broken or missing.

IMPORTANT: read directions for proper use



#### **ANTICAVITY**

sodium fluoride rinse

		mation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-548

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

**SODIUM FLUORIDE** (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION

0.1 mg in 1 mL

# Inactive Ingredients

Ingredient Name	Strength

water (UNII: 059QF0KO0R) sorbitol (UNII: 506T60A25R)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

POLOXAMER 407 (UNII: TUF2IVW3M2)

CODUM 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
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)	

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:69842- 548-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/20/2021		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/20/2021	

# **Labeler -** CVS Pharmacy, Inc (062312574)

# Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(69842-548)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Vi-Jon, LLC		088520668	manufacture(69842-548)	

Revised: 4/2023 CVS Pharmacy, Inc