

**ANTICAVITY- sodium fluoride rinse**  
**CVS Pharmacy, Inc.**

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

**Active ingredient**

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

**Purpose**

Anticavity

**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

## **Disclaimers**

\*This product is not manufactured or distributed by Kenvue, Inc., distributor of Listerine<sup>®</sup> Total Care Zero Alcohol Anticavity Mouthwash.

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

## **ADVERSE REACTION**

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

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CVS.com<sup>®</sup>

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Empty & Replace Cap

PLASTIC BOTTLE

how2recycle.info

## **Principal display panel**

Sealed with printed neckband for your protection.

IMPORTANT: Read directions for proper use.

CVS<sup>™</sup>

Anticavity Fluoride Mouthwash

SODIUM FLUORIDE & ACIDULATED PHOSPHATE TOPCAL SOLUTION

NO ADDED ALCOHOL

Fresh Mint Flavor

Compare to Listerine<sup>®</sup> Total Care Zero Alcohol Anticavity Mouthwash\*

6 Benefits:

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

1 L (1.05 QT) 33.8 FL OZ

Sealed with printed neckband for your protection

IMPORTANT: read directions for proper use.

## ANTICAVITY FLUORIDE MOUTHWASH

Sodium Fluoride & Acidulated Phosphate Topical Solution

NO ADDED ALCOHOL

Fresh Mint Flavor

**Compare to Listerine® Total Care Zero Alcohol Anticavity Mouthwash\***

**6 Benefits:** Restores enamel, Helps prevent cavities, Cleans the entire mouth,† Kills bad breath germs, Strengthens teeth, Freshens breath

1 L (1.05 QT) 33.8 FL OZ

L00187629C

### Drug Facts

<b>Active ingredient</b> Sodium fluoride 0.02% (0.01% w/v fluoride ion)	<b>Purpose</b> Anticavity
<b>Use</b> aids in the prevention of dental cavities	
<b>Warning</b> 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.	
<b>Directions</b> Adults and children 6 years of age and older: <ul style="list-style-type: none"> <li>■ use twice daily after brushing your teeth with a toothpaste</li> <li>■ vigorously swish 10 mL of rinse between your teeth for 1 minute and then spit out</li> <li>■ do not swallow the rinse</li> <li>■ do not eat or drink for 30 minutes after rinsing</li> <li>■ instruct children under 12 years of age in good rinsing habits (to minimize swallowing)</li> <li>■ supervise children as necessary until capable of using without supervision</li> </ul> Children under 6 years of age: consult a dentist or doctor	
<b>Other information</b> <ul style="list-style-type: none"> <li>■ store at controlled room temperature 20°-25°C (68°-77° F)</li> <li>■ cold weather may temporarily cloud this product</li> </ul>	
<b>Inactive ingredients</b> 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	

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 0 50428 05782 7

L00187629C

## ANTICAVITY

sodium fluoride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-548
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.1 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>EUCALYPTOL</b> (UNII: RV6J6604TK)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>THYMOL</b> (UNII: 3J50XA376E)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SPEARMINT OIL</b> (UNII: C3M81465G5)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## 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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	04/20/2021	

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

**Registrant** - Nice-Pak Products, LLC (119091520)

## Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(69842-548)