

**ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash**  
**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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**Drug Facts CVS 163.005/163AF-AG**

**Active Ingredient**

Sodium fluoride 0.0221% (0.01% fluoride ion)

**Purpose**

Antcavity

**Use**

aids in the prevention of dental cavities

**Warnings**

**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 it 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

**Inactive ingredients**

water, alcohol (21.6 %v/v), sorbitol, poloxamer 407, eucalyptol, flavor, methyl salicylate, menthol, phosphoric acid, sodium saccharin, thymol, disodium phosphate, sucralose, red 40, blue 1

**Other information**

- store at controlled room temperature 20° - 25° C (68° - 77° F)
- cold weather may temporarily cloud this product

\*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine Total Care Anticavity Mouthwash.

Distributed by: CVS Pharmacy, Inc.  
One CVS Drive, Woonsocket, RI 02895  
2017 CVS/pharmacy  
www.cvs.com 1-800-shop-CVS

## **principal display panel**

CVS Health

Compare to the active ingredient in Listerine Total Care Anticavity Mouthwash

Anticavity Fluoride Mouthwash

SODIUM FLUORIDE

6 Benefits:

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

Eucalyptus Mint

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

IMPORTANT: Read directions for proper use.

1 L (33.8 FL OZ)



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L0016122FA

## ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-163
<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>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>EUCALYPTOL</b> (UNII: RV6J6604TK)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>THYMOL</b> (UNII: 3J50XA376E)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<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:59779-163-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2008	
2	NDC:59779-163-86	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	09/15/2008	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/15/2008	

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

**Registrant** - Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(59779-163)