

**ANTICAVITY- sodium fluoride mouthwash**  
**CVS Pharmacy**

*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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**Restoring Anticavity Fluoride Mouthwash**  
**581.000-581AA-AB**

**Active ingredients**

Sodium fluoride 0.02% (0.009% 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 a day after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) 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

**Inactive ingredients**

water, alcohol (11%), sorbitol, poloxamer 407, propylene glycol, sodium benzoate, flavor, sodium phosphate, polysorbate 20, sodium saccharin, cetylpyridinium chloride, disodium phosphate, calcium disodium EDTA, blue 1

## **Adverse Reactions**

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS Quality

Money Back Guarantee

## **Disclaimer**

This product is not manufactured or distributed by Chattem Inc., distributor of Act Restoring Anticavity Fluoride Mouthwas Cool Mint.

## **Principal display panel**

CVS

Health

Compare to Act Restoring Fluoride Mouthwash Cool Mint\*

Anticavity

Restoring

Fluoride

Rinse

SODIUM FLUORIDE

- Restores enamel
- Helps remineralize soft spots
- Helps tooth decay prevention
- Freshens breath

Cooling Mint

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

IMPORTANT: Read directions for proper use

33.8 FL OZ (1L)



Compare to Act  
Restoring Anticavity  
Fluoride Mouthwash  
Cool Mint\*

Anticavity

# Restoring Fluoride Rinse

SODIUM FLUORIDE

- Restores enamel
- Helps remineralize soft spots
- Helps tooth decay prevention
- Freshens breath



Cooling Mint

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IMPORTANT: Read directions for proper use.

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L0016121FA

## ANTICAVITY

sodium fluoride mouthwash

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-581
Route of Administration	oral		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.2 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>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-581-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/24/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/24/2017	

**Labeler** - CVS Pharmacy (062312574)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(69842-581)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(69842-581)