

**ANTICAVITY- sodium fluoride rinse**  
**OLD EAST MAIN CO.**

*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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**Anticavity Fluoride Rinse**  
**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 immediately

**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 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, flavor, sodium lauryl sulfate, poloxamer 407, sodium benzoate, phosphoric acid, sodium saccharin, disodium phosphate, sucralose, red 40, blue 1

Since 1903 Rexall is a registered trademark of Rexall Sundown, Inc.

This product is not intended to replace brushing or flossing

100% Satisfaction Guaranteed

If you're not satisfied with this product for any reason, please call us so we can make you 100% satisfied.

(888)309-9030

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

### **principal panel display**

Since 1903

Rexall

Fluoride Anti-Cavity

Mouthwash

Sodium Fluoride and Acidulated

Phosphate Topical Solution

Alcohol-Free

6 BENEFITS

- Freshens breath
- Restores enamel
- Helps strengthen teeth to fight cavities
- Kills bad breath germs
- Burn free
- Cleans the entire mouth

IMPORTANT: read directions for proper use.

FRESH MINT

1 L (33.8 FL OZ)



# Fluoride Anti-Cavity Mouthwash

Sodium Fluoride and Acidulated Phosphate Topical Solution

Alcohol-Free

6

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- Cleans the entire mouth\*

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FRESH MINT



L0020081FA

## ANTICAVITY

sodium fluoride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-971
<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:Q80VPU408O)	FLUORIDE ION	0.02 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
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:55910-971-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/01/2021	

**Labeler** - OLD EAST MAIN CO. (068331990)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-971)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-971)

Revised: 12/2022

OLD EAST MAIN CO.