

**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, Bubble Gum**  
**004.002/004AE**

**Active ingredient**

Sodium fluoride 0.05% (0.02% 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, see professional assistance or contact a Poison Control Center immediately.

**Directions**

Adults and children 6 years of age and older:

- use once a day after brushing your teeth with a toothpaste
- vigorously swish 10 milliliters 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

**Inactive ingredients**

benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

**Adverse Reaction****Sealed with printed neckband for your protection**

Visit us at: [Rexall.com](http://Rexall.com) or call 1-866-4-REXALL

DISTRIBUTED BY Old East Main CO,

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

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

**Principal display panel**

DG health

Compare to Act Bubblegum Blowout

Anticavity Kids Fluoride Rinse

KIDS

Anticavity Fluoride Rinse

Strong Cavity Protection

Helps Strengthen Teeth

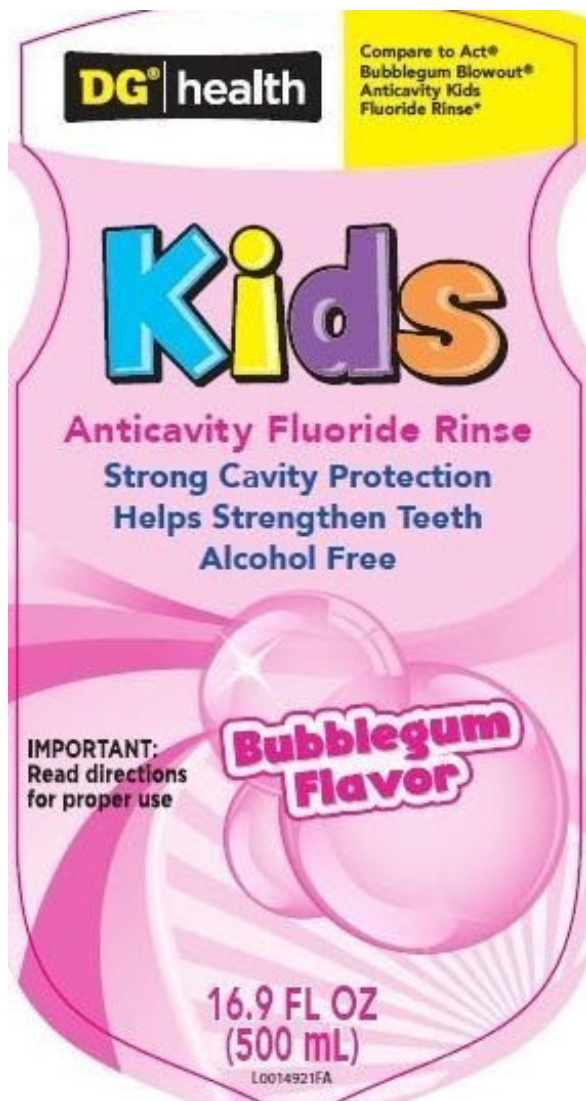
Alcohol Free

IMPORTANT: Read directions for proper use

Bubblegum Flavor

16.9 FL OZ

(500 mL)



## Principal display panel

Since 1903

Rexall

kids

Anticavity

Fluoride Rinse

Anticavity Fluoride Rinse

- Helps prevent cavities
- Helps strengthen teeth
- Alcohol free

IMPORTANT: read directions for proper use.

ADA Accepted

American Dental Association

Helps Prevent cavities

Bubblegum Flavor

500 mL (1 PT 0.9 FL OZ) 16.9 FL OZ



## ANTICAVITY

sodium fluoride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-030
<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	0.2 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)	
<b>CETYLPIRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**D&C RED NO. 33** (UNII: 9DBA0SBB0L)

**SODIUM BENZOATE** (UNII: OJ245FE5EU)

**SODIUM PHOSPHATE** (UNII: SE337SVY37)

**SACCHARIN SODIUM** (UNII: SB8ZUX40TY)

**SORBITOL** (UNII: 506T60A25R)

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-030-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2015	
2	NDC:55910-030-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/24/2015	

**Labeler** - Old East Main Co (068331990)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-030)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-030)

Revised: 9/2023

Old East Main Co