

**ANTICAVITY RINSE- sodium fluoride mouthwash**  
**Walgreen 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.*

-----

**Anticavity Fluoride Rinse 004.002/004AE**

**Active ingredient**

Sodium fluoride 0.05% (0.02%w/v fluoride ion)

**Purpose**

Anticavity rinse

**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, seek 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
- remove cap
- pour 10 milliliters (10 mL mark on inside of cap); do not fill above the 10mL mark
- 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

**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

**Other information**

- store at room temperature

**Adverse reaction**

Sealed with printed neckband for your protection

\*This product is not manufactured or distributed by Chattem, Inc., distributor of Act Anticavity Fluoride Rinse.

Questions or comments? 1-800-925-4733

Distributed by: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015

100% satisfaction guaranteed walgreens.com (c)2015 Walgreen Co.

Patent D604,628

004.002/004AE

**principal display panel**

Well at Walgreens

children's

ANTICAVITY - FLUORIDE

Mouth Rinse

Anticavity Fluoride Rinse

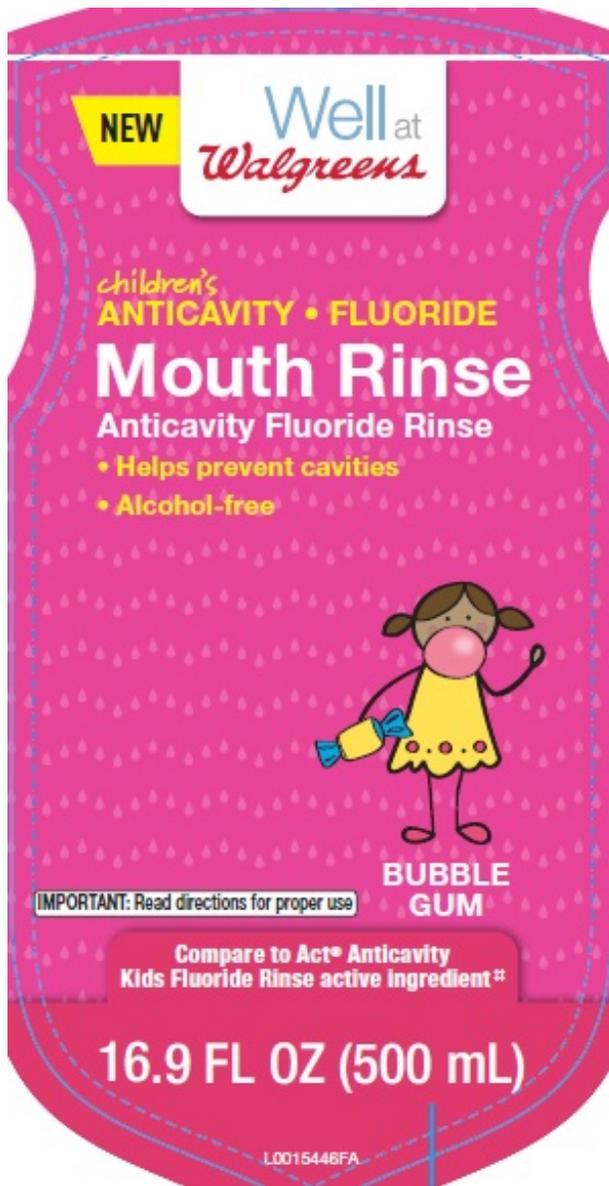
Helps prevent cavities

- Alcohol-free
- BUBBLE GUM

**IMPORTANT:** Read directions for proper use

Compare to Act Anticavity Kids Fluoride Rinse active ingredient

16.9 FL OZ (500 mL)



## ANTICAVITY RINSE

sodium fluoride mouthwash

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0014 |
| Route of Administration | ORAL           |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION      | .05 kg in 100 L |

### Inactive Ingredients

| Ingredient Name                   | Strength |
|-----------------------------------|----------|
| BENZYL ALCOHOL (UNII: LKG8494WBH) |          |

|   |  |
|---|--|
| EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF) |  |
| CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) |  |
| EDETATE DISODIUM (UNII: 7FLD91C86K)         |  |
| SODIUM PYROPHOSPHATE (UNII: O352864B8Z)     |  |
| POLOXAMER 407 (UNII: TUF2IVW3M2)            |  |
| POLYSORBATE 80 (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:0363-0014-44 | .5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/27/2002           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355                                  | 06/27/2002           |                    |

**Labeler** - Walgreen Co (008965063)

**Registrant** - Vi Jon (790752542)

### Establishment

| Name   | Address | ID/FEI    | Business Operations    |
|--------|---------|-----------|------------------------|
| Vi Jon |         | 790752542 | manufacture(0363-0014) |