

**ANTICAVITY RINSE- sodium fluoride mouthwash**  
**Retail Business Services, LLC**

*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% (0.2% w/v fluoride ion)

**Purpose**

Anticavity Rinse

**Use**

aids in the prevention of dental cavities

**Warnings**

**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 year 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 10 mL 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 year 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, poloxomer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

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

Distributed by Foodhold, U.S.A, LLC

4201 Walden Avenue

Landover, MD 20785 1-877-846-9949

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Quality Guaranteed or your money back

## **principal display panel**

CAREONE

Compare to Act Kids Anticavity Fluoride Rinse\*

CHILDREN'S

ANTICAVITY

FLUORIDE RINSE

Strong Cavity

Protection

Alcohol Free

BUBBLE GUM FLAVOR

Sealed with printed neckband for your protection

IMPORTANT: Read directions for proper use.

18 FL OZ (532 mL)



## ANTICAVITY RINSE

sodium fluoride mouthwash

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:72476-204 |
| <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) | SODIUM FLUORIDE   | 0.5 mg in 1 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)                       |          |
| <b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)   |          |
| <b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)             |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)                     |          |
| <b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F) |          |
| <b>POLOXAMER 407</b> (UNII: TUF21VW3M2)                        |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                       |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                     |          |

|  |  |
|--|--|
| <b>D&amp;C RED NO. 33</b> (UNII: 9DBA05BB0L) |  |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)    |  |
| <b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)   |  |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)   |  |
| <b>SORBITOL</b> (UNII: 506T60A25R)           |  |
| <b>WATER</b> (UNII: 059QF0KO0R)              |  |

| <b>Packaging</b> |                  |  |                      |                    |
|------------------|------------------|--|----------------------|--------------------|
| #                | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
| 1                | NDC:72476-204-44 | 532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/10/2010           |                    |
| 2                | NDC:72476-204-77 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/10/2010           |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final          | part355                                  | 03/10/2010           |                    |

**Labeler** - Retail Business Services, LLC (967989935)

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

| <b>Establishment</b> |         |           |                        |
|----------------------|---------|-----------|------------------------|
| Name                 | Address | ID/FEI    | Business Operations    |
| Vi Jon, LLC          |         | 790752542 | manufacture(72476-204) |