

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash
DZA Brands, 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.

Anticavity Fluoride Rinse, Mint
213.002/213AE rev 2

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 the inside of cap); do not fill above the 10 mL mark
- vigorously swish 10 milliliters of rinse between your teeth for 1 minute 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

water, sorbitol, menthol, methyl salicylate, flavor, cetylpyridinium chloride, sodium saccharin, poloxamer 407, polysorbate 20, propylene glycol, sodium phosphate, disodium phosphate, calcium disodium EDTA, disodium EDTA, sodium benzoate, potassium sorbate, benzyl alcohol, green 3, yellow 5

disclaimer

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

adverse reaction

DISTRIBUTED BY: DZA Brands, LLC, 2110 Executive Drive, Salisbury NC 28147

For Product questions or concerns contact us at 1-866-322-2439

Please include UPC code number from package.

Principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

IMPORTANT: READ DIRECTIONS FOR PROPER USE

healthy

accents

alcohol-free

anticaviy

fluoride rinse

mint flavor

- helps prevent cavities
- helps strength teeth
- freshens breath

compare to the active ingredient of Act Anticavity Fluoride Rinse

18 FL OZ (532 mL)



ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55316-213 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.2 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |

| |
|--|
| CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) |
| POLOXAMER 407 (UNII: TUF2IVW3M2) |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| SODIUM PHOSPHATE (UNII: SE337SVY37) |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) |
| EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955) |
| sodium benzoate (UNII: OJ245FE5EU) |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) |
| BENZYL ALCOHOL (UNII: LKG8494WBH) |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:55316-213-44 | 532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/07/2011 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 01/07/2011 | |

Labeler - DZA Brands, LLC (090322194)

Registrant - Vi-Jon, LLC (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 790752542 | manufacture(55316-213) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 088520668 | manufacture(55316-213) |