ANTICAVITY- sodium fluoride rinse Liberty Procurement, Inc.

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, Bubble gum 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

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 toothpaste
- remove cap
- pour 10 mililiters (10 mL mark on inside of cap); do not fill above the 10 mL mark
- vigorously swish 10 mililiters 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, cetylpridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

Distributed by Liberty Procurement, Inc.

Union, NJ 07083 USA

Visit us at: www.facevalues.com

SATISFACTION GUARANTEED Or Your Money Back

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

principal display panel

Sealed with printed neckband for your protection

COREVAUES

Compare to the active ingredient in Act Bubble Gum Kids*

KIDS Anticavity FLUORIDE RINSE

BUBBLE GUM FLAVOR

- Strong cavity protection
- Helps strengthen teeth

IMPORTANT: Read directions for proper use.

ADA

Accepted

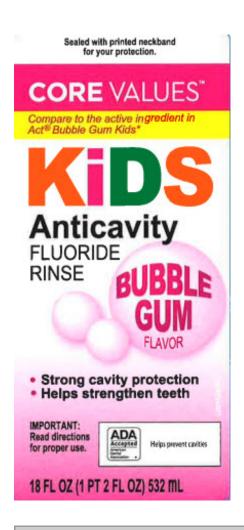
American

Dental

Association

Helps prevent cavities

18 FL OZ (1 PT 2 FL OZ) 532 mL



ANTICAVITY

sodium fluoride rinse

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63940-004

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 |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955) | |
| CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| 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:63940- 004-44 | 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 - Liberty Procurement, Inc. (804085293)

Registrant - Vi-Jon, LLC (790752542)

| Establishment | | | |
|---------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Vi-Jon, LLC | | 790752542 | manufacture(63940-004) |

| Establishment | | | |
|---------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Vi-Jon, LLC | | 088520668 | manufacture(63940-004) |

Revised: 1/2023 Liberty Procurement, Inc.