

ANTICAVITY- sodium fluoride rinse
TOPCO Associates 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.

Top Care 971.001 971AB

Active Ingredients

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity rinse

Use

aids in the prevention of dental cavities

Warning

for this product

Keep out of Reach of Children

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately

Directions

Adults and children 6 years of age and older:

- use twice daily after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) 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 20° - 25° C (68° - 77° F)

- cold weather may temporarily cloud this product

Inactive ingredients

water, sorbitol, propylene glycol, poloxamer 407, sodium lauryl sulfate, flavor, sodium benzoate, phosphoric acid, eucalyptol, methyl salicylate, thymol, sodium saccharin, menthol, disodium phosphate, sucralose, Mentha viridis (spearmint) leaf oil, Mentha piperita (peppermint) oil, red 40, blue 1

Disclaimer

This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine Total Care Zero Anticavity Mouthwash.

This TOPCARE product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

Adverse reactions section

DISTRIBUTED BY TOPCO ASOCIATES LLC

ELK GROVE VILLAGE, IL 60007

1-888-423-0139 TOPCO

topcare@topco.com www.topcarebrand.com

principal display panel

COMPARE TO LISTERINE TOTAL CARE ZERO ANTICAVITY MOUTHWASH

Top Care

everyday

ALCOHOL FREE - FLUORIDE

Anticavity

Mouthwash

SODIUM FLUORIDE AND ACIDULATED PHOSPHATE TOPICAL SOLUTION

FRESH MINT

6 Benefits

- Alcohol free
- Helps prevent cavities
- Strengthens teeth
- Restores enamel
- Kills bad breath germs
- Cleans entire mouth*

*This product is not intended to replace brushing or flossing

IMPORTANT:

Read direction for proper use.

33.8 FL OZ (1 QT 1.8 FL OZ) 1 L



COMPARE TO LISTERINE®
TOTAL CARE ZERO
ANTICAVITY MOUTHWASH*

 **TopCare**®
everyday™

ALCOHOL FREE • FLUORIDE

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L0013787FB

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ANTICAVITY

sodium fluoride rinse

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-971 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.02 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| water (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| PHOSPHORIC ACID (UNII: E4GA8884NN) | |
| EUCALYPTOL (UNII: RV6J6604TK) | |
| THYMOL (UNII: 3J50XA376E) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| SPEARMINT OIL (UNII: C3M81465G5) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:36800-971-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/19/2013 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part355 | 09/19/2013 | |

Labeler - TOPCO Associates LLC (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
| Vi-Jon, LLC | | 790752542 | manufacture(36800-971) |

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| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
| Vi-Jon, LLC | | 088520668 | manufacture(36800-971) |

Revised: 5/2022

TOPCO Associates LLC