

ANTICAVITY- sodium fluoride rinse
H E Butt

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.

HEB 971.001 971AB

active ingredients

Sodium fluoride 0.0% (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 right away.

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

Questions

Call 1-888-593-0593

guarantee

100% GUARANTEE promise

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money.

You have our word on it.

Adverse reactions section

MADE WITH PRIDE AND CARE FOR H-E-B

SAN ANTONIO, TX 78204

Disclaimer

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Listerine Total Care Zero Alcohol Anticavity Fresh Mint Mouthwash.

principal display panel

Compare to Listerine Total Care Zero Alcohol

H-E-B

Alcohol Free

ANTICAVITY

MOUTHWASH

SODIUM FLUORIDE AND ACIDULATED PHOSPHATE TOPCAL SOLUTION

- Helps strengthen teeth to fight cavities
- Restored enamel
- Kills bad breath germs
- Cleans the entire mouth**
- Alcohol Free

- Fresh Mint

IMPORTANT: read directions for proper use

33.8 FL OZ (1.05 QT) 1 L



ANTICAVITY

sodium fluoride rinse

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37808-119 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | 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: TUF21VW3M2) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| PHOSPHORIC ACID (UNII: E4GA8884NN) | |
| EUCALYPTOL (UNII: RV6J6604TK) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |
| 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:37808-119-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/20/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 04/20/2021 | |

Labeler - H E Butt (007924756)

Registrant - Vi-Jon, LLC (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 790752542 | manufacture(37808-119) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 088520668 | manufacture(37808-119) |

