

ANTICAVITY- sodium fluoride mouthwash
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 435.000-435AA

Active Ingredient

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

Purpose

Anticavity

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, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 6 years of age and older:

- use twice a day 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

Inactive ingredients

water, alcohol (8%), hydrogen peroxide, poloxamer 407, sodium saccharin, sucralose, menthol, phosphoric acid, disodium phosphate, flavor

Other information

- store at room temperature (59°-77°F)

other information

Contains peroxide which releases oxygen while whitening. This may cause the bottle to inflate slightly or release air when opened.

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine Healthy White Vibrant Anticavity Mouthrinse

Adverse reactions

DISTRIBUTED BY TOPCO ASSOCIATES, LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com www.topcarebrand.com

principal display panel

COMPARE TO LISTERINE HEALTHYWHITE

Top Care

everyday

FLUORIDE

Whitening

Antivavity Mouthwash

SODIUM FLUORIDE AND ACIDULATED PHOSPHATE TOPICAL SOLUTION

FRESH MINT

- 5 days to whiter teeth
- Begins working on contact
- Safely whitens teeth
- Kills germs that cause bad breath

IMPORTANT: Read direction for proper use.

16 FL OZ (1 PT) 473 mL

COMPARE TO LISTERINE®
HEALTHYWHITE™*

 **TopCare**®
everyday™

FLUORIDE

Whitening

Anticavity Mouthwash

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L0015094FB

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ANTICAVITY

sodium fluoride mouthwash

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-803 |
| Route of Administration | oral | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | FLUORIDE ION | 0.2 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | |
| POLOXAMER 407 (UNII: TUF21VW3M2) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| PHOSPHORIC ACID (UNII: E4GA8884NN) | |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:36800-803-45 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/15/2015 | |
| 2 | NDC:36800-803-43 | 474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/15/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 09/15/2015 | |

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 790752542 | manufacture(36800-803) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 088520668 | manufacture(36800-803) |