

ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Walgreen Co

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.

Mouthrinse
124

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, antiplaque

Use

help control plaque that leads to gingivitis

Warnings

For this product

Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. These may be signs of periodontitis, a serious form of gum disease.

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

Directions

adults and children 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then spit out; do not swallow the rinse

children 6 years to under 12 years of age: supervise use

children under 6 years of age: do not use

Other information

- this rinse is not intended to replace brushing or flossing

- cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59°-77°F)

Inactive ingredients

water, alcohol 21.6%, sorbitol solution, flavor, poloxamer 407, benzoic acid, sucralose and/or sodium saccharin, sodium benzoate, propylene glycol alginate, FD&C yellow no. 6, FD&C blue no. 1

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

*This product is not manufactured or distributed by Johnson + Johnson Healthcare Products, distributor of Listerine Antiseptic Vanilla Mint

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED

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MADE IN U.S.A. WITH U.S. AND FOREIGN COMPONENTS

124.000/124AE

principal display panel

Well at Walgreens

ANTISEPTIC

Mouth Rinse

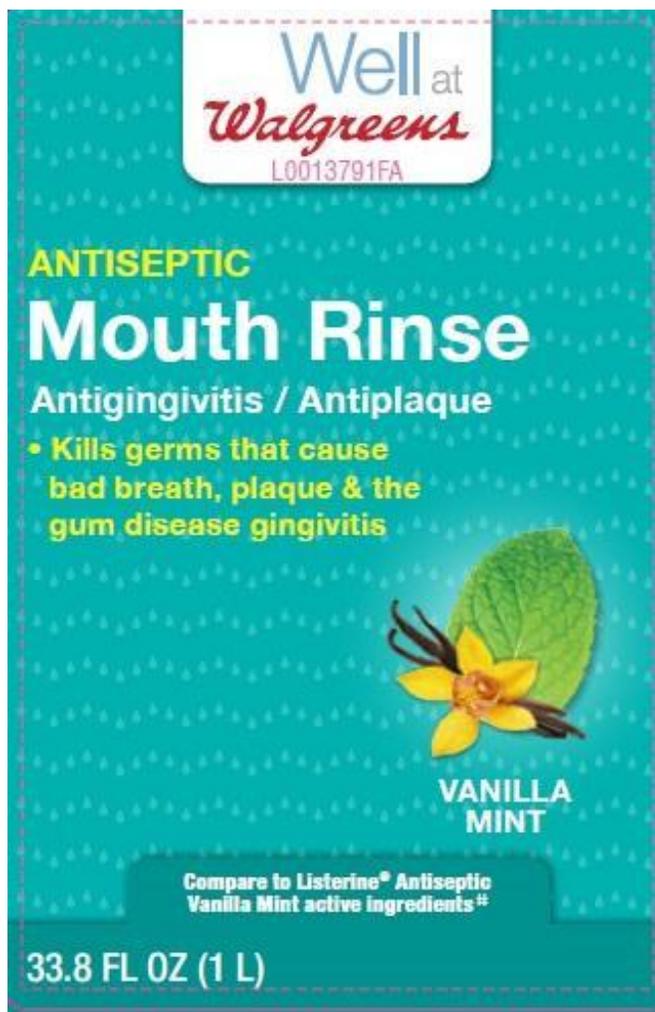
Antigingivitis/Antiplaque

- Kills germs that cause bad breath, plaque + the gum disease gingivitis

VANILLA MINT

Compare to Listerine Antiseptic Vanilla Mint active ingredients*

33.8 FL OZ (1L)



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0080 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK) | EUCALYPTOL | 0.92 mg in 1 mL |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 0.42 mg in 1 mL |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 0.60 mg in 1 mL |
| THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E) | THYMOL | 0.64 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|----------|
| WATER (UNII: 059QF0K00R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| SORBITOL (UNII: 506T60A25R) | |

| | |
|---|--|
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| BENZOIC ACID (UNII: 8SKN0B0MM) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0363-0080-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/10/2013 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| OTC mono graph not final | part356 | 09/10/2013 | |

Labeler - Walgreen Co (008965063)

Registrant - Vi-Jon (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| Vi-Jon | | 790752542 | manufacture(0363-0080) |

Revised: 5/2020

Walgreen Co