# ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol 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.

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# Top Care 664.003 664AU

# **Active ingredients**

Eucalyptol 0.0692%

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

#### Do not use

if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

# Stop use

and ask a dentist if gingivitis, bleeding, or redness persists for more than 2 weeks.

# 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 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

children under 12 years of age - consult a dentist or doctor

this rinse is not intended to replace brushing or flossing

## **Inactive ingredients**

water, alcohol 21.6%, sorbitol solution, flavor, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, FD&C green no.3

#### **ADA Council Statement**

The ADA council on Scientific Affairs Acceptance of CVS/pharmacy Blue Mint Antiseptic Mouthwash is based on its finding that the product is effectie in helping to prevent and reduce gingivitis and plague above the gumline, when used as directed.

#### **Disclaimer**

This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine

#### **Adverse Reactions**

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# principal display panel

COMPARE TO LISTERINE

TopCare

everyday

**Antiseptic** 

Mouthwash

ANTIGINVITIS/ANTIPLAQUE

#### **BLUE MINT**

- For better oral hygiene & fresher breath
- Kills germs that cause bad breath, plaque & the gum disease gingivitis

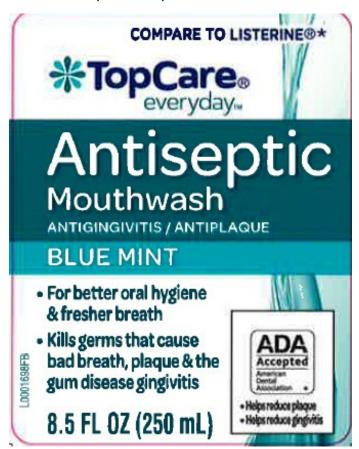
#### **ADA**

## Accepted

American Dental Association

- Helps reduce plaque
- Helps reduce gingivitis

8.5 FL OZ (250 mL)



#### **ANTISPETIC**

eucalyptol, menthol, methyl salicylate, thymol mouthwash

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-664 |
| Route of Administration | ORAL           |                    |               |

| Active Ingredient/Active Moiety  |                      |                    |  |
|--|----------------------|--------------------|--|
| Ingredient Name  | Basis of<br>Strength | Strength           |  |
| EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)             | EUCALYPTOL           | 0.92 mg<br>in 1 mL |  |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)                   | MENTHOL              | 0.42 mg<br>in 1 mL |  |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ4LPZ) | METHYL SALICYLATE    | 0.60 mg<br>in 1 mL |  |
|  |                      | 0.64               |  |

u.64 mg in 1 mL

| Inactive Ingredients                |          |  |  |
|-------------------------------------|----------|--|--|
| Ingredient Name                     | Strength |  |  |
| WATER (UNII: 059QF0KO0R)            |          |  |  |
| ALCOHOL (UNII: 3K9958V90M)          |          |  |  |
| SORBITOL (UNII: 506T60A25R)         |          |  |  |
| POLOXAMER 407 (UNII: TUF2IVW3M2)    |          |  |  |
| BENZOIC ACID (UNII: 85KN0B0MIM)     |          |  |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) |          |  |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)  |          |  |  |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) |          |  |  |

| Packaging |                      |   |                         |                       |
|-----------|----------------------|---|-------------------------|-----------------------|
| #         | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:36800-<br>664-69 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 10/26/1992              |                       |
| 2         | NDC:36800-<br>664-77 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 10/26/1992              |                       |
| 3         | NDC:36800-<br>664-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/26/1992              |                       |
| 4         | NDC:36800-<br>664-12 | 1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/26/1992              |                       |

| Marketing Information   |   |                         |                       |
|-------------------------|---|-------------------------|-----------------------|
| Marketing<br>Category   | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph not final | part356                                     | 10/26/1992              |                       |
|                         |   |                         |                       |

# Labeler - Topco Associates LLC (006935977)

# Registrant - Vi-Jon, LLC (790752542)

| Establishment |         |           |                        |
|---------------|---------|-----------|------------------------|
| Name          | Address | ID/FEI    | Business Operations    |
| Vi-Jon, LLC   |         | 790752542 | manufacture(36800-664) |

| Establishment |         |           |                            |
|---------------|---------|-----------|----------------------------|
| Name          | Address | ID/FEI    | <b>Business Operations</b> |
| Vi-Jon, LLC   |         | 088520668 | manufacture(36800-664)     |

Revised: 5/2022 Topco Associates LLC