ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Pharmacy Value Alliance 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.

Blue Mint Antiseptic Mouthrinse 664.003/664AT rev 2-AU

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, antiplaque

use

helps 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

Other information

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, sodium saccharin, sodium benzoate, FD&C green no.3

claims

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Cool Mint Listerine Antiseptic mouthwash.

"The ADA council on Scientific Affairs' Acceptance of Premier Value Blue Mint Antiseptic Mouth Rinse is based on its finding that the product is

effective in helping to prevent and reduce gingivitis and plaque above the gumline, when used as directed."

Adverse Reactions

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund

DISTRIBUTED BY

CHAIN DRUG CONSORTIUM

3301 NW BOCA RATON BLVD

SUITE 101, BOCA RATON, FL 33431

Principal Display Panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION
COMPARE TO COOL MINT LISTERINE ANTSEPTIC MOUTHWASH

Premier

Value

Antiseptic

Mouthrinse

Antigingivitis/Antiplaque

blue mint

kils germs that cause

bad breath, plaque & the gum disease gingiviis

ADA

Accepted

American

Dental

Association

1 L (33.8 FL OZ)



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-664

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: 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 Date | Marketing End Date |
| 1 | NDC:68016- 664-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2009 | |
| 2 | NDC:68016- 664-77 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2009 | |

| Marketing Information | | | |
|-------------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part356 | 05/15/2009 | |
| | | | |

Labeler - Pharmacy Value Alliance LLC (101668460)

Registrant - Vi-Jon, LLC (790752542)

| Establishment | | | |
|---------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Vi-Jon, LLC | | 790752542 | manufacture(68016-664) |

| Establishment | | | |
|---------------|---------|--------|----------------------------|
| Name | Address | ID/FEI | Business Operations |

| Vi-Jon, LLC | 088520668 | manufacture(68016-664) | |
|-------------|-----------|------------------------|--|
|-------------|-----------|------------------------|--|

Revised: 12/2022 Pharmacy Value Alliance LLC