

ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash
United Natural Foods, Inc. dba UNFI

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 rev2-664AU

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.

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, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, flavor, green 3

TEP

Sealed With Printed Neckband For Your Protection

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Listerine.

Adverse Reactions

Like it or let us make it right.

That's our quality promise.

855-423-2630

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02908 USA

DSP-TN-21091

DSP-MO-20087

Principal display panel

NDC 41163-055-86

compare to Cool Mint Listerine Antiseptic Mouthwash active ingredients*

EQUALINE

antiseptic

mouthrinse

antigingivitis/antiplaque

- kills germs that cause bad breath, plaque and gingivitis gum disease

blue mint

1L (33.8 FL OZ)



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41163-055 |
| 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: 2150YA276E) (THYMOL - UNII:2150YA276E) | THYMOL | 0.64 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| SORBITOL (UNII: 506T60A25R) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| 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:41163-055-77 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/29/1994 | |
| 2 | NDC:41163-055-12 | 1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/29/1994 | |
| 3 | NDC:41163-055-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/29/1994 | |
| 4 | NDC:41163-055-13 | 1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/29/1994 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356 | 07/29/1994 | |

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Registrant - Vi-Jon, LLC (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 790752542 | manufacture(41163-055) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 088520668 | manufacture(41163-055) |