ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash Retail Business Services, 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.

Antiseptic Mouthrinse 318.003/318AH-AI

TEP

Sealed With Printed Neckband For Your Protection

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 gingvitis

Warnings

for this product

Do not use

if you have painful or swollen gums, pus from the fum 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 teaspoonfruls) between teeth for 30 seconds than 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 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Original Listerine Antiseptic Mouthwash.

Adverse Reaction

DISTRIBUTED BY FOODHOLD, U.S.A., LLC

LANDOVER, MD 20785

1-877-846-9949

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Quality guaranteed or your money back.

principal display panel

CAREONE

Compare to Original Listerine Antiseptic Mouthwash*

ANTISEPTIC

MOUTH RINSE

ANTIGINGIVITIS/ANTIPLAQUE

KILLS GERMS THAT CAUSE BAD BREATH, PLAQUE AND THE GUM DISEASE GINGIVITIS



Compare to Original Listerine® Antiseptic Mouthwash*

ANTISEPTIC

MOUTH RINSE ANTIGINGIVITIS/ANTIPLAQUE

KILLS GERMS THAT CAUSE BAD BREATH, PLAQUE AND THE GUM DISEASE GINGIVITIS

ORIGINAL FLAVOR

L0002613FE

33.8 FL OZ (1.05 QT) 1L

ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72476-318 |
| 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) | | |
| BENZOIC ACID (UNII: 85KN0B0MIM) | | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | |
| CARAMEL (UNII: T9D99G2B1R) | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:72476- 318-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/13/1989 | |
| 2 | NDC:72476- 318-12 | 1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/13/1989 | |
| 3 | NDC:72476- 318-69 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/13/1989 | |

| Marketing Information | | | |
|-------------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part356 | 03/13/1989 | |
| | | | |

Labeler - Retail Business Services, LLC (967989935)

Registrant - Vi-Jon, LLC (790752542)

| Establishment | | | |
|---------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Vi-Jon, LLC | | 790752542 | manufacture(72476-318) |

| Establishment | | | |
|---------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Vi-Jon, LLC | | 088520668 | manufacture(72476-318) |

Revised: 6/2023 Retail Business Services, LLC