ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash Lidl US, 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.

Drug Facts

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

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 twice a day 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 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

Questions or comments?

1-844-344-5071

Disclaimer

This product is manufactued or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine Original Antiseptic Mouthwash

Adverse reaction

DISTRIBUTED BY

Lidl US, LLC

3500 S. Clark Street

Arlington, VA 22202

QUESTIONS?

1-844-5071

www.Lidl.com

318.003/318AH

principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Kills Germs That Cause Bad Breath, Plaque, & Gingivitis Gum Disease

ANTISEPTIC

MOUTHWASH

ORIGINAL AMBER

ADA

ACCEPTED

American

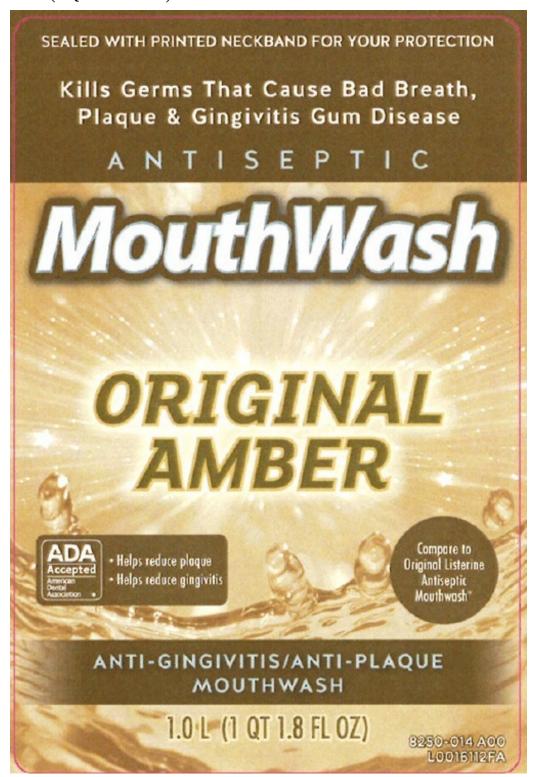
Dental

Association

- Helps reduce plaque
- Helps reduce gingivitis

Compare to Original Listerine Antiseptic Mouthwash

ANTI-GINGIVITIS/ANTI-PLAQUE



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

| Pro | duct | Infor | mation |
|-----|------|-------|--------|
|-----|------|-------|--------|

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71141-157

| 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: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E) | THYMOL | 0.64 mg in 1 mL | |

| Inactive Ingredients | | |
|------------------------------------|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |
| ALCOHOL (UNII: 3K9958V90M) | | |
| BENZOIC ACID (UNII: 8 SKN0 B0 MIM) | | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | |
| CARAMEL (UNII: T9D99G2B1R) | | |

| ı | Packaging | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:71141-157- 32 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/09/2017 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part356 | 02/09/2017 | |
| | | | |

Labeler - Lidl US, LLC (079389709)

Registrant - Vi-Jon (790752542)

| Establishment | | | |
|---------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Vi-Jon | | 790752542 | manufacture(71141-157) |

Revised: 4/2019 Lidl US, LLC