

ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Western Family Foods, Inc

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

Active ingredients

Eucalyptol 0.0692%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Purpose

Antigingivitis, antiplaque

Use

Use help control plaque that leads to gingivitis

Warnings

Warnings

Do not use

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

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

Keep out of reach of children.

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

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

Other information cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59°-77°F)

Inactive ingredients

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 Safeway 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

Disclaimer

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

Adverse Reactions

Proudly dist. by Western Family Foods, Inc., P.O. Box 4057, Portland, OR 97208

www.westernfamily.com

Safety Sealed

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Principal display panel

WESTERN

FAMILY

ANTISEPTIC

Mouth Rinse

Kills Germs that

cause Bad Breath,

Plaque + the gum

disease Gingivitis

Blue Mint

ADA

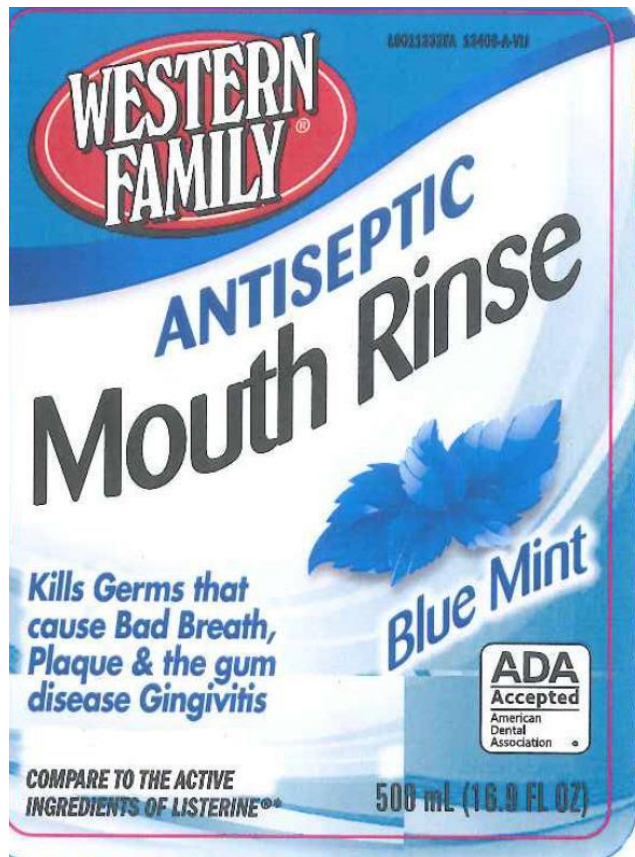
Accepted

American

Dental

Association

COMPARE TO THE ACTIVE
INGREDIENTS OF LISTERINE
500 mL (16.9 FL OZ)



| | |
|--|---|
| Drug Facts | |
| Active ingredients | Purpose |
| Eucalyptol 0.092%, Menthol 0.042%..... | Antigingivitis, Antiplaque |
| Methyl salicylate 0.060%, Thymol 0.064%..... | Antigingivitis, Antiplaque |
| Use helps control plaque that leads to gingivitis | |
| Warnings | |
| 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 | |
| <small>*The ADA Council on Scientific Affairs' Acceptance of Western Family® 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.</small> | |
| <small>* This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine®. Proudly Dist. by Western Family Foods, Inc., P.O. Box 4057, Portland, OR 97208 U.S.A. Copyright 2011, Marca Registrada www.westernfamily.com</small> | |
| SEAL WITH PRINTED NECKBAND FOR YOUR PROTECTION | |
| DSP-TN-15000 DSP-MQ-34 SDS-TN-15012 | |
| L0011332BA 13405-A-VII | |

ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55312-664 |
| 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: 8SKN0B0MM) | |
| 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:55312-664-86 | 1000 mL in 1 BOTTLE, PLASTIC | | |
| 2 | NDC:55312-664-77 | 500 mL in 1 BOTTLE, PLASTIC | | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part356 | 03/15/1998 | |

Labeler - Western Family Foods, Inc (192166072)

Registrant - Vi-Jon (790752542)

| Establishment | | | |
|----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Vi-Jon | | 790752542 | manufacture(55312-664) |