

TARTAR CONTROL - eucalyptol mouthwash

Western Family

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 0.024%
Methyl salicylate 0.060% thymol 0.064%

Purpose

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, flavoring, PEG-40 hydrogenated castor oil, poloxamer 407, benzoic acid, zinc chloride, sucralose and/or sodium saccharin, sodium benzoate, yellow 6, red 40

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

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

WESTERN

FAMILY

Antiseptic Mouthwash

TARTAR

CONTROL

Helps Control tartar

helps remove Germs That Cause Plaque and Gingivitis

Freshens Breath

Brightens Teeth

Citrus

COMPARE TO THE ACTIVE

INGREDIENTS OF LISTERINE
1 L (33.8 FL OZ)



TARTAR CONTROL

eucalyptol mouthwash

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55312-210 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------|-------------------|------------------|
| EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK) | EUCALYPTOL | .092 mL in 100 L |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | .042 mL in 100 L |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y) | METHYL SALICYLATE | .060 mL in 100 L |
| THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E) | THYMOL | .064 mL in 100 L |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|---------------------------------------------------------------|--|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| SORBITOL (UNII: 506T60A25R) | |
| POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| ZINC CHLORIDE (UNII: 86Q357L16B) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------|----------------------|--------------------|
| 1 | NDC:55312-210-86 | 1 L in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part356 | 09/23/2010 | |

Labeler - Western Family (192166072)

Registrant - Vi Jon (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|---------------------|
| Vi Jon | | 790752542 | manufacture |

Revised: 3/2012

Western Family