ANTISEPTIC MOUTH RINSE - eucalyptol, menthol, methyl salicylate, thymol mouthwash Geiss, Destin + Dunn

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

Eucalyptol 0.092%

Menthol 0.042%

Methyl sailcylate 0.060%

THYMOL 0.064%

Purpose

Antigingivitis

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 • this rinse is not intended to replace brushing or flossing 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 the spit out; do not swallow children under 12 years of age - consult a dentist or doctor

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

Distributed By:

Geiss, Destin + Dunn, Inc 385 Highway 74 South

Peachtree, GA 30269

www.valuelabels.com

Sealed With Printed Neckband For Your Protection

GoodSense

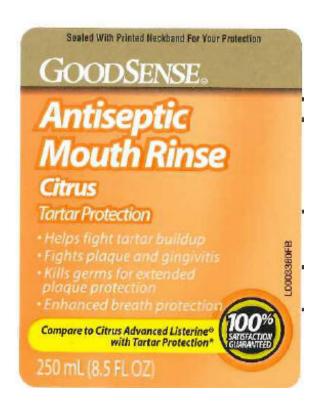
Antiseptic

Citrus

Tartar Protection

- •Helps fight tartar buildup
- •Fights plaque and gingivitis

- •Kill germs for extended plaque protection
- •Enhanced breath protection Compare to Citrus Advanced Listerine with Tartar Protection 250 mL (8.5 FL OZ)



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75981-210 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|--------------------------|----------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK) | EUCALYPTOL | 0.092 kg in 100 L | |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 0.042 kg in 100 L | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y) | METHYL SALICYLATE | 0.060 kg in 100 L | |
| THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E) | THYMOL | 0.064 kg 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: 8 SKN0 B0 MIM) | |
| 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:75981-210-69 | 0.25 L in 1 BOTTLE, PLASTIC | | | |
| 2 | NDC:75981-210-86 | 1.5 L in 1 BOTTLE, PLASTIC | | | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part348 | 07/09/1993 | |
| | | | |

Labeler - Geiss, Destin + Dunn (076059836)

Registrant - Vi Jon (790752542)

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

Revised: 4/2012 Geiss, Destin + Dunn