**LISTERINE ULTRACLEAN ANTISEPTIC COOL MINT- eucalyptol, menthol, methyl salicylate, and thymol mouthwash**
**Johnson & Johnson Consumer 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.*

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**Listerine Ultraclean Antiseptic**
**Cool Mint**

***Drug Facts***

**Active ingredients**

Eucalyptol 0.092%
Menthol 0.042%
Methyl salicylate 0.060%
Thymol 0.064%

**Purposes**

Antiplaque/antigingivitis

**Uses**

helps prevent and reduce:
- plaque
- gingivitis

**Warnings**

**Do not use** in children under 12 years of age

**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**
- rinse full strength for 30 seconds with 20 ml (2/3 fluid ounce or 4 teaspoonfuls) morning and night
- do not swallow

**Other information**
- store at controlled room temperature 20° - 25° C (68° – 77° F)
- cold weather may cloud this product. Its antiseptic properties are not affected.

**Inactive ingredients**

water, alcohol (21.6%), sorbitol solution, flavor, poloxamer 407, benzoic acid, zinc chloride, sodium benzoate, sucralose, sodium saccharin, green no. 3

**Questions?**

call toll-free **1-888-222-0182** or **215-273-8755** (collect)

Dist: Johnson & Johnson Healthcare Products
Division of McNEIL-PPC, Inc.
Skillman, NJ 08558-9418 USA

**PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label**

**LISTERINE®**
**ULTRACLEAN™**
WITH EVERFRESH™ TECHNOLOGY

**ANTISEPTIC**

Controls Tartar Build-up
Kills Plaque & Gingivitis
Germs, Keeps Breath
Fresh for Hours

***vs. brushing alone**

COOL MINT®

**500 mL (1.05 Pt)**

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# ULTRACLEAN™

## WITH EVERFRESH™ TECHNOLOGY

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30005701

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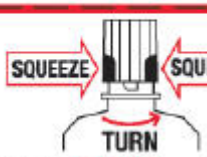
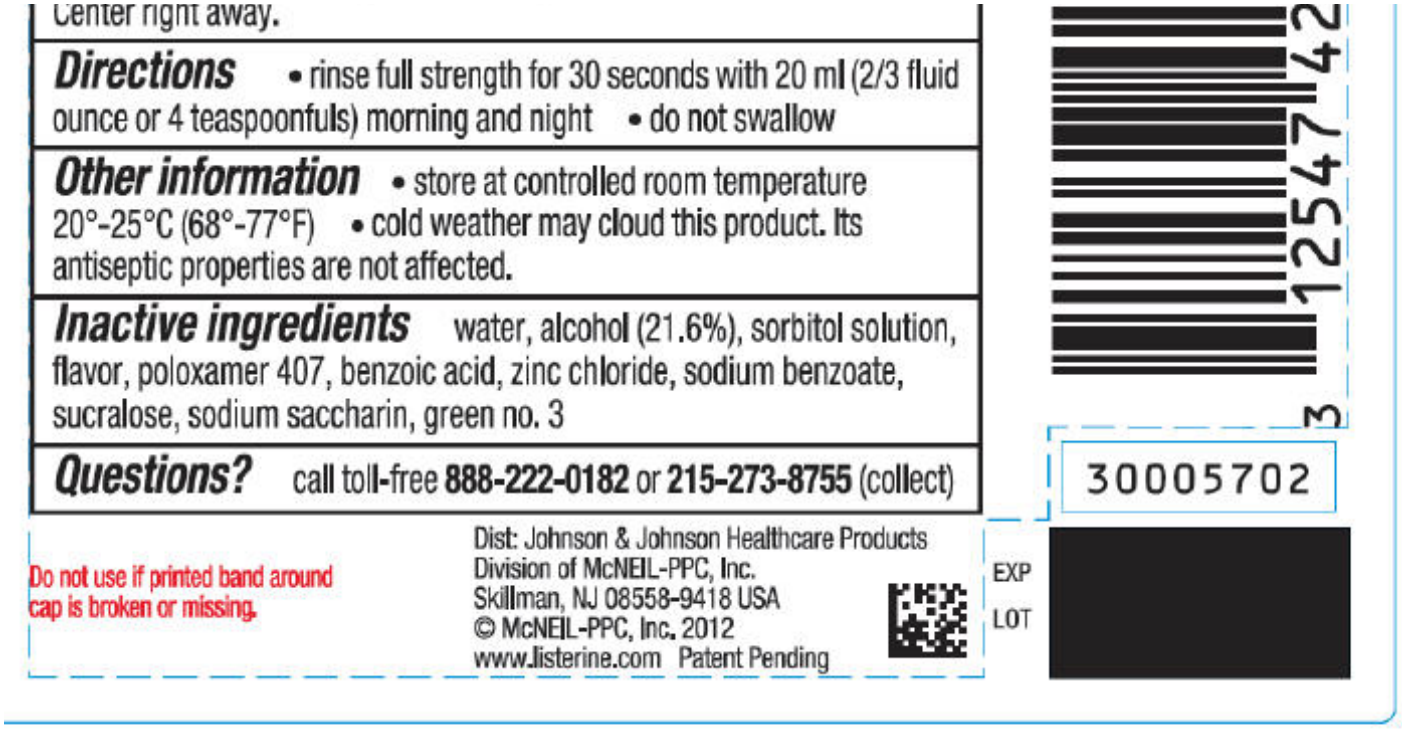



TO OPEN: SQUEEZE smooth areas on cap and TURN.
TO CLOSE: Turn cap until it locks.



0 268





# LISTERINE ULTRACLEAN ANTISEPTIC COOL MINT

eucalyptol, menthol, methyl salicylate, and thymol mouthwash

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:42002-447 |
| **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, Unspecified Form** (UNII: L7T10EIP3A) (Menthol, Unspecified Form - UNII:L7T10EIP3A) | Menthol, Unspecified Form | 0.42 mg in 1 mL |

| | | |
|---|---|---|
| **Methyl Salicylate** (UNII: LAV5U5022Y) (Salicylic Acid - UNII:O414PZ4LPZ) | Methyl Salicylate | 0.6 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: 8SKN0B0MIM) | |
| **Zinc Chloride** (UNII: 86Q357L16B) | |
| **Sodium Benzoate** (UNII: OJ245FE5EU) | |
| **Sucralose** (UNII: 96K6UQ3ZD4) | |
| **Saccharin Sodium** (UNII: SB8ZUX40TY) | |
| **FD&C Green No. 3** (UNII: 3P3ONR6O1S) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:42002-447-95 | 95 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2012 | 12/01/2023 |
| **2** | NDC:42002-447-73 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2012 | 12/01/2023 |
| **3** | NDC:42002-447-72 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2012 | 12/01/2023 |
| **4** | NDC:42002-447-71 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2012 | 12/01/2023 |
| **5** | NDC:42002-447-70 | 1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2012 | 12/01/2023 |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH NOT FINAL | part356 | 07/09/2012 | 12/01/2023 |

## Labeler - Johnson & Johnson Consumer Inc. (002347102)

Revised: 1/2019 Johnson & Johnson Consumer Inc.