

LISTERINE COOL MINT ANTISEPTIC- eucalyptol, menthol, methyl salicylate, 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.

Listerine Cool Mint Antiseptic Mouthwash

Drug Facts

Active ingredient

Eucalyptol 0.092%

Menthol 0.042%

Methyl Salicylate 0.060%

Thymol 0.064%

Purpose

Antiplaque/antigingivitis

Uses

helps prevent and reduce: • plaque • gingivitis

Warnings

Do not use in children under 12 years of age

Ask a dentist

Ask a dentist if symptoms persist, new symptoms appear, or conditions worsen after regular use

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

- this rinse is not intended to replace brushing or flossing
- store at room temperature
- cold weather may cloud this product. Its antiseptic properties are not affected.

Inactive ingredients

Water, Alcohol (21.6%), Sorbitol, Poloxamer 407, Benzoic Acid, Sodium Saccharin, Sodium Benzoate, Flavor, Green 3

Questions?

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

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 1.5 L Bottle Label

ANTIGINGIVITIS/ANTIPLAQUE MOUTHWASH

LISTERINE®

COOL MINT®

ANTISEPTIC

FOR A FRESHER &

CLEANER MOUTH THAN

BRUSHING ALONE

ADA

Accepted

American

Dental

Association®

1.5 L (1 Qt 1Pt 2.7 Fl Oz)

**KILLS 99.9% OF GERMS
THAT CAUSE BAD BREATH,
PLAQUE & GINGIVITIS**

30040767

ANTIINGIVITIS / ANTIPLAQUE MOUTHWASH

LISTERINE®
COOL MINT®
ANTISEPTIC

FOR A FRESHER &
CLEANER MOUTH THAN
BRUSHING ALONE



30053228

1.5 L (1 Qt 1 Pt 2.7 Fl Oz)



CLINICALLY PROVEN. Kills Germs by Millions on Contact.

Use **COOL MINT® LISTERINE®** Antiseptic twice daily to help: **Prevent & Reduce Plaque**
Prevent & Reduce Gingivitis **Freshen Breath** **Kill Germs Between Teeth**

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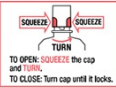
Do not use if printed band around cap is broken or missing.



• Helps prevent and reduce plaque
• Helps prevent and reduce gingivitis



Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
Skillman, NJ 08558 © J&JCI 2022 www.listerine.com
Pat. www.jcipsats.com



THIS FORMULA IS NOT SOLD TO ANY RETAILER AS A STORE BRAND.

The LISTERINE® bottle design is a registered trademark of Johnson & Johnson.



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EXP
LOT

LISTERINE COOL MINT ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69968-0791 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 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 |
| EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK) | EUCALYPTOL | 0.92 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| POLOXAMER 407 (UNII: TUF21VW3M2) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| SORBITOL (UNII: 506T60A25R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69968-0791-1 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/21/2023 | |
| 2 | NDC:69968-0791-9 | 95 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/21/2023 | |
| 3 | NDC:69968-0791-3 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/21/2023 | |
| 4 | NDC:69968-0791-2 | 1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/21/2023 | |
| 5 | NDC:69968-0791-4 | 3700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/21/2023 | |
| 6 | NDC:69968-0791-5 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/21/2023 | |
| 7 | NDC:69968-0791-6 | 2 in 1 PACKAGE | 03/21/2023 | |
| 7 | | 1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356 | 03/21/2023 | |

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 8/2023

Johnson & Johnson Consumer Inc.