LISTERINE FRESHBURST ANTISEPTIC- eucalyptol, menthol, unspecified form, 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.

LISTERINE ® FRESHBURST ® ANTISEPTIC

Drug Facts

Active ingredients	***Purposes***
Eucalyptol (0.092%)	Antiplaque/antigingivitis
Menthol (0.042%)	Antiplaque/antigingivitis
Methyl Salicylate (0.060%)	Antiplaque/antigingivitis
Thymol (0.064%)	Antiplaque/antigingivitis

Uses

helps prevent and reduce:
- plaque
- gingivitis

Warnings

Do not use in children under 12 years of age

Ask a dentist if symptoms persist

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

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
- 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% v/v), Sorbitol, Poloxamer 407, Benzoic Acid, Sodium Saccharin, Flavor, Sodium Benzoate, Yellow 10, 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 - 1500 mL Bottle Label

ANTISEPTIC

LISTERINE ®

FRESHBURST ®

FOR A FRESHER &

CLEANER MOUTH THAN

BRUSHING ALONE

ADA

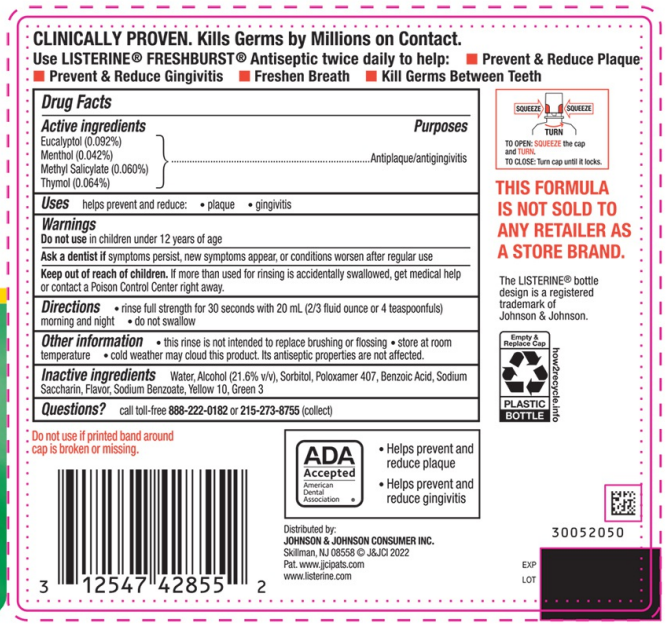
Accepted

American

Dental

Association ®

1.5 L (1 Qt 1 Pt 2.7 fl oz)



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eucalyptol, menthol, unspecified form, methyl salicylate, and thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69968-0239
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)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0239-5	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/17/2018	
2	NDC:69968-0239-2	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2019	
3	NDC:69968-0239-1	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/18/2018	
4	NDC:69968-0239-3	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/28/2018	
5	NDC:69968-0239-8	2 in 1 PACKAGE	04/24/2020	10/11/2023
5	NDC:69968-0239-3	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	08/17/2018	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 1/2023 Johnson & Johnson Consumer Inc.