LISTERINE FRESHBURST 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 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

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% 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

ANTIGINGIVITIS / ANTIPLAQUE MOUTHWASH

LISTERINE ®

FRESHBURST ®

ANTISEPTIC

FOR A FRESHER &

CLEANER MOUTH THAN

BRUSHING ALONE

ADA

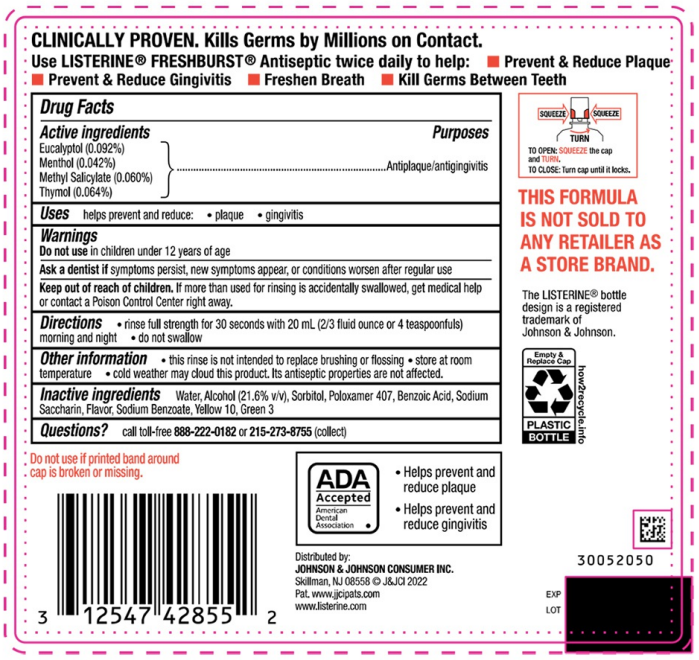
Accepted

American

Dental

Association ®

1.5 L (1 Qt 1 Pt 2.7 Fl Oz)



LISTERINE FRESHBURST ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69968-0792
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:69968-0792-5	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2023	
2	NDC:69968-0792-3	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2023	
3	NDC:69968-0792-1	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2023	
4	NDC:69968-0792-2	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/21/2023	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 8/2023 Johnson & Johnson Consumer Inc.