LISTERINE COOL MINT ANTISEPTIC- eucalyptol, menthol, unspecified form, methyl salicylate, and thymol liquid
Navajo Manufacturing Company 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

Drug Facts

Active ingredients

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

Purposes

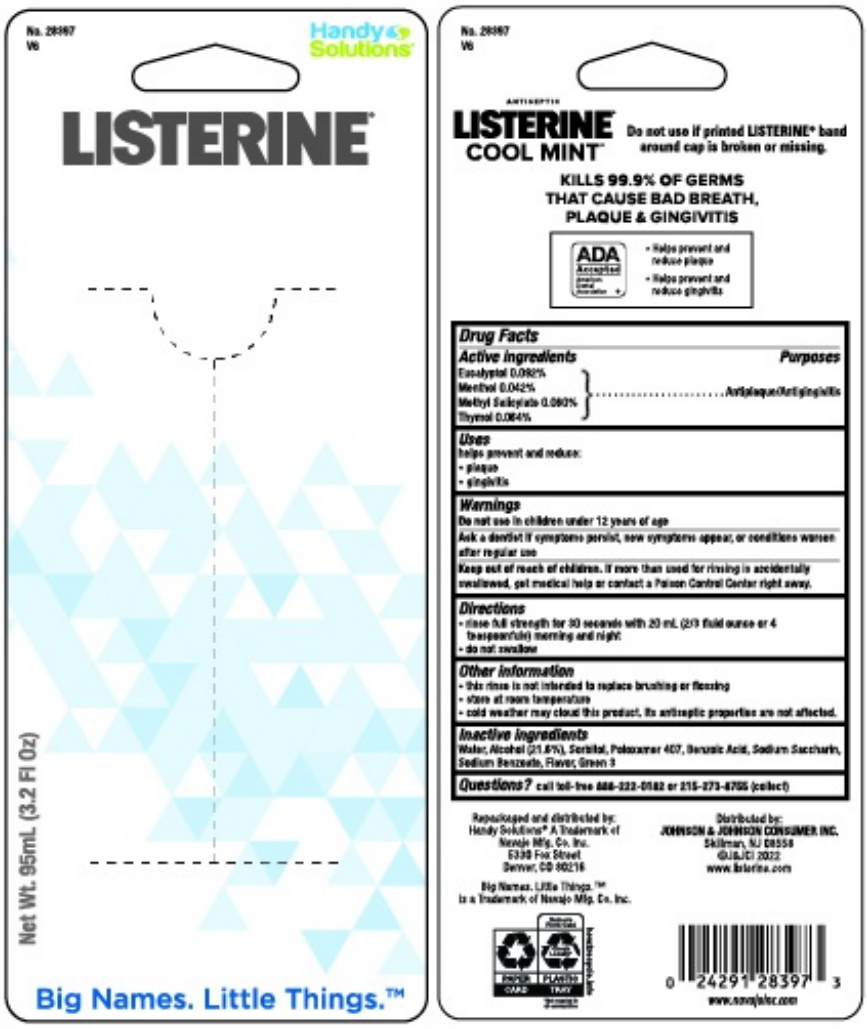
Antiplaque/antigingivitis

Uses

Helps prevent and reduce:

- Plaque
- Gingivitis

Warnings



Do not use in children under 12 years of age

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

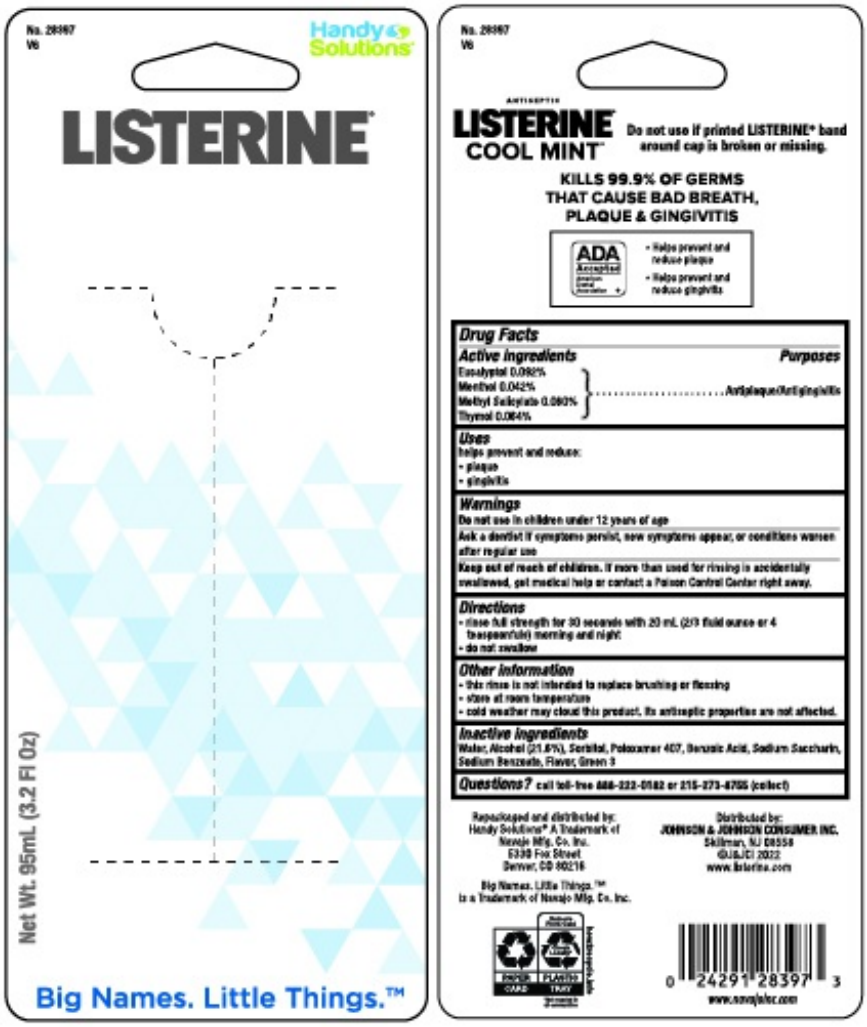
Water, Alcohol (21.6%), Sorbitol, Poloxamer 407, Benzoic Acid, Sodium Saccharin,

Sodium Benzoate, Flavor, Green 3

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL



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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67751-216(NDC:69968-0550)
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)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-216-01	1 in 1 BLISTER PACK	03/02/2023	
1		95 mL in 1 BOTTLE; 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	12/03/2018	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-216) , repack(67751-216)

Revised: 3/2023 Navajo Manufacturing Company Inc.