LISTERINE ANTISEPTIC- 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.

Listerine Antiseptic

Drug Facts

Active ingredients

Purposes

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

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 room temperature
- cold weather may cloud this product. Its antiseptic properties are not affected.

Inactive ingredients

water, alcohol (26.9%), benzoic acid, poloxamer 407, sodium benzoate, caramel

Questions?

call **1-888-222-0182**, weekdays

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

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

LISTERINE®

ORIGINAL ANTISEPTIC

Kills Germs that Cause Bad Breath, Plaque & the Gum Disease Gingivitis

ADA Accepted American Dental Association®

500 mL (1.05 Pt)

LISTERINE ORIGINAL

ANTISEPTIC

Kills Germs that Cause Bad Breath, Plaque & the Gum Disease Gingivitis



500 mL (1.05 Pt)

American Dental Association ®

30018224



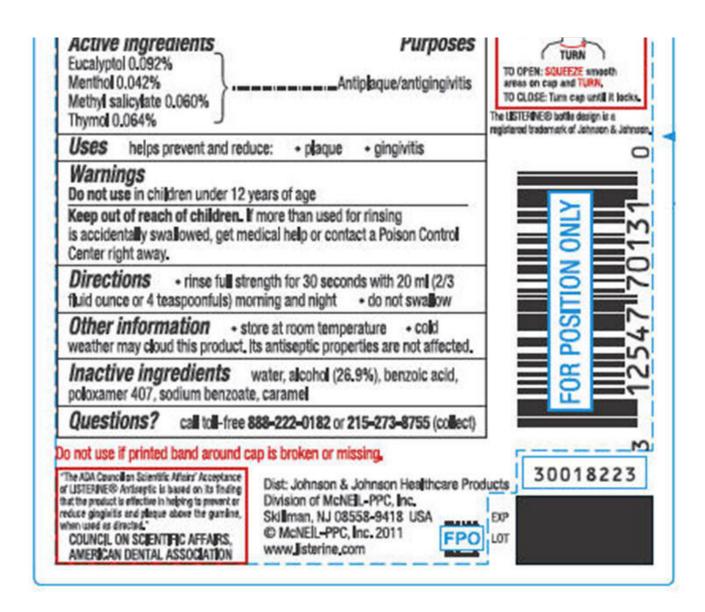
DEEPER CLEAN
THAN BRUSHING ALONE

30018222



Drug Facts





LISTERINE ANTISEPTIC

eucalyptol, menthol, methyl salicylate, and thymol mouthwash

Product Information	roduct Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42002-401				
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 mI		
Thymol (UNII: 3J50XA376E) (Thymol - UNII:3J50XA376E)	Thymol	0.64 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Alcohol (UNII: 3K9958V90M)			
Benzoic Acid (UNII: 8 SKN0 B0 MIM)			
Poloxamer 407 (UNII: TUF2IVW3M2)			
Sodium Benzoate (UNII: OJ245FE5EU)			
Caramel (UNII: T9D99G2B1R)			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:42002-401- 73	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2012		
2	NDC:42002-401- 72	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2012		
3	NDC:42002-401-71	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2012		
4	NDC:42002-401- 70	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2012		
5	NDC:42002-401- 63	3700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2012		
6	NDC:42002-401- 94	2 in 1 PACKAGE	02/21/2012		
6	NDC:42002-401- 70	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
7	NDC:42002-401- 95	95 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2012		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part356	0 2/2 1/2 0 12			

Labeler - Johnson & Johnson Consumer Inc. (002347102)

Revised: 12/2018 Johnson & Johnson Consumer Inc.