### ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol liquid Family Dollar (FAMILY WELLNESS)

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### Kalaya Breath Refresh Antiseptic Oral Rinse-updated label for NDC

# **Active ingredient**

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

# Purposes

Antiplaque/antigingivitis

### Uses

helps prevent and reduce

- plaque
- gingivitis

# Warning

#### Do not use

in children under 12 years of age.

#### Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

# Keep out of reach of children under 6 years of age

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away

#### Directions

- adults and children 12 years of age and older: vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse.
- children 6 years to under 12 years of age: supervise use
- children under 6 years of age: do not use

## Other information

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

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## Inactive ingredients

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

#### Questions or comments

Call

# Principal display panel

\*Compare to the active ingredients in Listerine®

Antiseptic

Mouthwash

Eucalyptol (0.092%)

Menthol (0.042%)

Methyl salicylate (0.060%)

Thymol (0.064%)

Antiplaque/antigingivitis

Kill germs that cause plaque, gingivitis, bad breath

Helps to control and prevent plaque that leads to gingivitis

ORIGINAL

L (qt fl oz)

\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Listerine®.

### TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

**DISTRIBUTED BY:** 

Package label

NDC XXXXX-XXX *Compare to the active ingredients in Listerine®	Drug Facts         Active ingredients       Purposes         Eucalyptol (0.092%)       Methyl Salicylate (0.060%)         Methyl Salicylate (0.060%)       Thymol (0.064%)			
Antiseptic <b>Mouthwash</b> Eucalymtol (0.002%)	Uses helps prevent and reduce ■ plaque ■ gingivitis Warnings Do not use in children under 12 years of age. Stop use and ask a dentist if ■ gingivitis, bleeding, or redness persists for more than 2 weeks ■ you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.			
Eucalyptol (0.092%) Menthol (0.042%) Methyl salicylate (0.060%) Thymol (0.064%)	<ul> <li>Keep out of reach of children under 6 years of age. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</li> <li>Directions         <ul> <li>adults and children 12 years of age and older: vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse.</li> <li>children 6 years to under 12 years of age: supervise use</li> <li>children 6 years of age: do not use</li> </ul> </li> </ul>			
Antiplaque/antigingivitis √ Kills germs that cause plaque, gingivitis, bad breath	Other information           store at room temperature         cold weather may cloud this product. Its antiseptic properties are not affected.              this rinse is not intended to replace brushing or flossing             Inactive ingredients			
$\checkmark$ Helps to control and prevent plaque that leads to gingivitis	water, alcohol (26.9% v/v), poloxamer 407, sodium benzoate, benzoic acid, caramel Questions or comments? Call X-XXX-XXXX DAYS & TIMES & ZONE *This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Listerine®.			
0RIGINAL 81,290081 945,247-014	Distributed by: (Specific to customer's labeling guide. Must state either: manufacturer, packer, or distributor.)			
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Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:55319-089	
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 (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL	0.42 mg in 1 mL	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)			METHYL SALICYLA	TE 0.6 mg in 1 mL	
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)			THYMOL	0.64 mg in 1 mL	

**Ingredient Name** 

Strength

WATER (UNII: 059QF0K00R)							
ALCOHOL (UNII: 3K9958V90M)							
POLOXAMER 407 (UNII: TUF2IVW3M2)							
BENZOIC ACID (UNII: 85KN0B0MIM)							
SODIUM BENZOATE (UNII: OJ245FE5EU)							
CARAMEL (UNII: T9D99G2B1R)							
Product Characteristics							
Color	yellow	Score					
Shape		Size					
Flavor		Imprint Code					
Contains							
Packaging							
# Item Code P	Package Description		Marketing Star Date	t Marketing End Date			
	9- 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		07/01/2025				
2NDC:55319- 089-25250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		07/01/2025					
Marketing Information							
Marketing Applica Category	tion Number or Mo Citation	onograph	Marketing Start Date	Marketing End Date			
OTC Monograph Drug M022			07/01/2025				

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 6/2025

Family Dollar (FAMILY WELLNESS)