ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Valu Merchandisers Co

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.

Antiseptic Mouthrinse 318.003/318AH-AI

Active Ingredients

Eucalyptol 0.092% Menthol 0.042%

Methyl Salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

for this product

Do Not use

if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist

if gingivitis, bleeding, or redness persists for more than 2 weeks

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

adults and children 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then spit out; do not swallow

children under 12 years of age - consult a dentist or doctor

this rinse is not intended to replace brushing or flossing

Other information

cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59°-77°F).

Inactive ingredients

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

Questions

Call 1-888-593-0593

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Original Listerine Antiseptic Listerine

Adverse Reaction

Best Choice 100% Guarantee

Proudly Distributed By:

VALU MERCHANDISERS, CO

5000 KANSAS AVE

KANSAS CITY, MO 66106

principal display panel

Best

Choice

Sealed With Printed Neckband For Your Protection

COMPARE TO THE ACTIVE INGREDIENTS IN LISTERINE**

ANTISEPTIC

Mouth Rinse

ANTIGINGIVITIS/ANTIPLAQUE

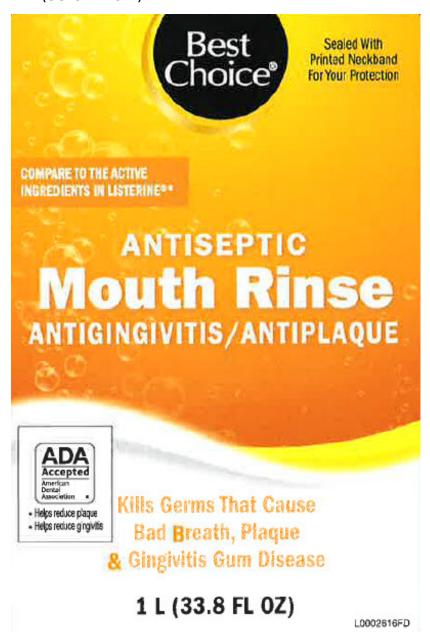
ADA

Accepted

American Dental Association

- Helps reduce plaque
- Helps reduce gingivitis

Kills Germs That Cause Bad Breath, Plaque & Gingivitis Gum Disease 1 L (33.8 FL OZ)



ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-003	
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	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ4LPZ)	METHYL SALICYLATE	0.60 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)				
BENZOIC ACID (UNII: 85KN0B0MIM)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
CARAMEL (UNII: T9D99G2B1R)				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:63941- 003-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/09/1995	
	2	NDC:63941- 003-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/09/1995	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/09/1995	

Labeler - Valu Merchandisers Co (868703513)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63941-003)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(63941-003)	

Revised: 6/2023 Valu Merchandisers Co