ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash Chain Drug Consortium

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

Adult and children 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonsful) 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

Disclaimer

*This product is not manufactured or directed by Johnson & Johnson Healthcare Poroducts, distributor of Original Listerine Antiseptic Mouthwash

Adverse Reactions

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

DISTRIBUTED BY

Pharmacy Value Alliance LLC

407 East Lancaster Avenue.

Wayne, PA 19087

principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

COMPARE TO ORIGINAL LISTERINE ANTISEPTIC MOUTHWASH*

Premier

Value

Antiseptic

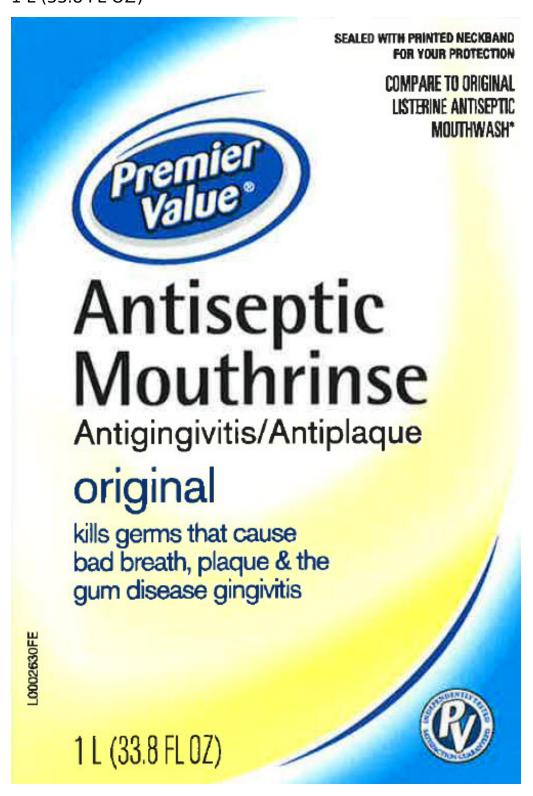
Mouthrinse

Antigingivitis/Antiplaque

original

kills germs that cause

bad breath, plaque & the gum disease gingivitis 1 L (33.8 FL OZ)



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-318
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)		

P	ackaging			
#	Item Code	Code Package Description Mar		Marketing End Date
1	NDC:68016- 318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2003	
2	NDC:68016- 318-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2003	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/19/2003	
IIIIGI			

Labeler - Chain Drug Consortium (101668460)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(68016-318)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(68016-318)

Revised: 6/2023 Chain Drug Consortium