ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash HEB

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 manufactered or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine Mouthwash

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Adverse reactions

MADE WITH PRIDE AND CARE FOR H-E-B

SAN ANTONIO, TX 78204

100% GUARANTEE promise

If you arn't completely pleased with this product, we'll be happy to replace it or refund your money. you have our word on it.

Principal display panel

Compare to Listerine* H-E-B

Original

ANTISEPTIC

ANTIGINGIVITIS/ANTIPLAQUE

MOUTHWASH

- Helps Fight Germs That Cause Bad Beath
- Fights Plaque & Gingivitis

ADA Accepted

American Dental Association

- Helps reduce plaque
- Helps reduce gingivitis

33.8 FL OZ (1 QT) 1L



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-318
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)		

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808- 318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2009	
2	NDC:37808- 318-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2009	
3	NDC:37808- 318-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2009	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part356	05/21/2009	

Labeler - HEB (007924756)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37808-318)
Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37808-318)

Revised: 6/2023

HEB