

MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Old East Main 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

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Active ingredient

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 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

Disclaimer

100% Satisfaction Guaranteed

If you're not satisfied with this product for any reason, please call us so we can make you 100% satisfied.

(888)309-9030

Since 1903 Rexall is a registered trademark of Rexall Sundown, Inc.

Distributed by Old East Main Co.

100 Mission Ridge

Goodlettsville, TN 37072

DSP-TN-21091

DSP-MO-20087

principal display panel

DG health

Compare to Original Listerine Antiseptic Mouthwash*

ANTISEPTIC

MOUTHWASH

Antigingivitis/Antiplaque

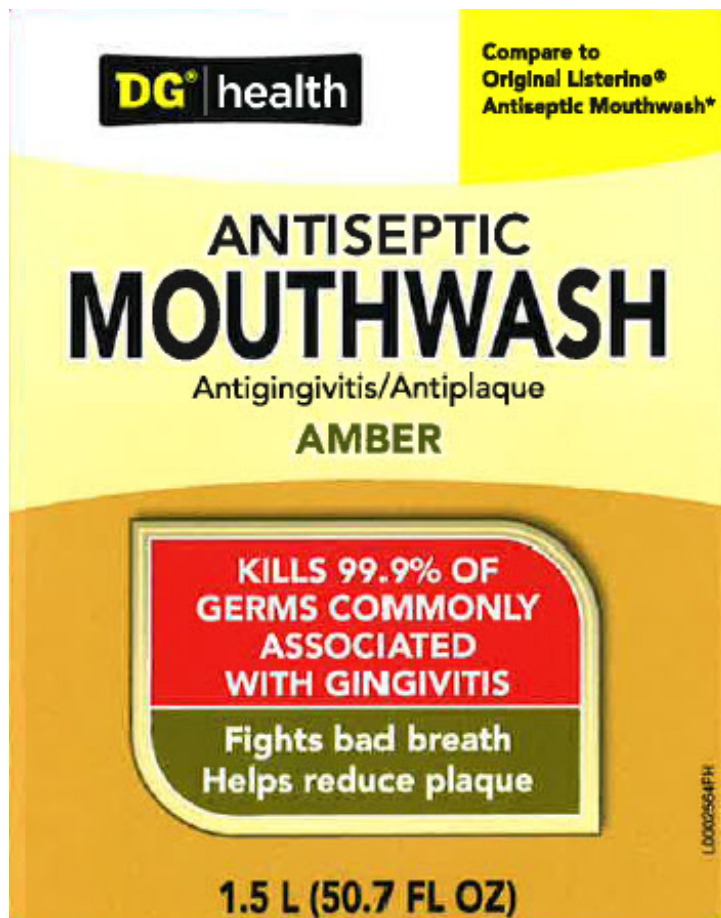
AMBER

KILLS 99.9% OF GERMS COMMONLY ASSOCIATED WITH GINGIVITIS

Fights bad breath

Helps reduce plaque

1.5L (50.7 FL OZ)



principal display panel

Since 1903

Rexall

Amber

Antiseptic

Mouthwash

Antigingivitis/Antiplaque

- Kills 99.9% of germs commonly associated with gingivitis
- Fights bad breath
- Helps reduce plaque

ADA Accepted

American Dental Association

- Helps reduce plaque
- Helps reduce gingivitis

1.5 L (1 QT 1 PT 2.7 FL OZ) 50.7 FL OZ



MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-318
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: 8SKN0B0MIM)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
CARAMEL (UNII: T9D99G2B1R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-318-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/2001	
2	NDC:55910-318-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/2001	
3	NDC:55910-318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/2001	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part356	01/11/2001	

Labeler - Old East Main Co (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-318)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-318)

Revised: 6/2023

Old East Main Co