ANTISEPTIC- eucayptol, menthol, methyl salicylate, thymol mouthwash Perrigo Direct, Inc.

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 saliclate 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 gun line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serous 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 teaspoonsfuls) 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 properites are not affected. Store at room temperature (59°-77°F).

Inactive ingredients

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

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

Distributed by

Perrigo Direct, Inc.

Peachtree City, GA 30269

1-888-593-0593

GoodSense is a registered trademark of L. Perrigo Company.

DSP-TN21091

DSP-MO-20087

Principal display panel

Sealed With Printed Neckband For Your Protection

GoodSense

NDC 5084-318-12

Antiseptic Mouth Rinse

Original

Kills Germs That Cause

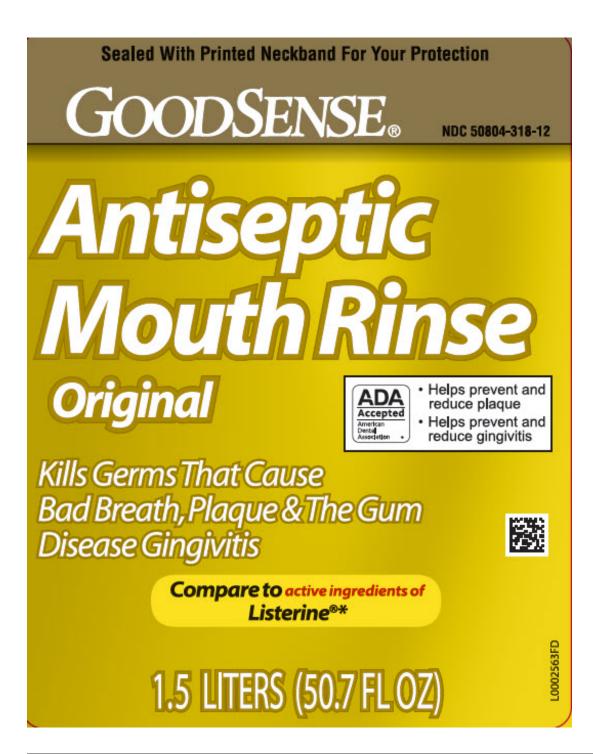
Bad Breath, Plague & The Gum Disease Gingivitis

ADA Accepted American Dental Association

- Helps prevent and reduce plaque
- Helps prevent and reduce gingivitis

Compare to active ingredients of Listerine

1.5 Liters (50.7 FLOZ)



ANTISEPTIC

eucayptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50804-318

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of
Strength

Strength

00000

EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	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	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50804- 318-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1990		
2	NDC:50804- 318-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1990		
3	NDC:50804- 318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1990		
4	NDC:50804- 318-13	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1990		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/15/1990	

Labeler - Perrigo Direct, Inc. (076059836)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(50804-318)

Revised: 6/2023 Perrigo Direct, Inc.