

MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash
United Natural Foods, Inc. dba UNFI

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 is 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

TEP

Sealed With Printed Neckband For Your Protection

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Corporation, distributor of Original Listerine Antiseptic Mouthwash.

Adverse reactions

Like it or let us make it right.

That's our quality promise.

8556-423-2630

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02908 USA

DSP-TN-21091

DSP-MO-20087

Principal display panel

NDC 41163-318-86

Compare to Original Listerine Antiseptic Mouthwash active ingredients*

EQUALINE

antiseptic

mouthrinse

antigingivitis/antiplaque

- kills germs that cause bad breath, plaque and gingivitis gum disease

amber

1.L (33.8 FL OZ)

NDC 41163-318-86

compare to
Original Listerine®
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active ingredients*

EQUALINE®

**antiseptic
mouthrinse**
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• kills germs that cause
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amber

L0020737FB

1L (33.8 FL OZ)

MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-318
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: TUF21VW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-318-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2005	
2	NDC:41163-318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2005	
3	NDC:41163-318-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2005	
4	NDC:41163-318-13	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/04/2005	

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(41163-318)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(41163-318)