

**ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate,
thymol mouthwash
Cariba International**

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.

Cariba 318.003/318AI

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

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

Adverse reactions

Distributed by:

Cariba International

P.O. Box 1208

Safety Harbor, Florida 34695

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US AND FOREIGN

COMPONENTS

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CARIBA

ANTISEPTIC

MOUTHWASH

ANTINGIVITIS/ANTIPLAQUE

ORIGINAL

Kills germs that cause Bad Breath,

Plaque & the gum disease Gingivitis

250 mL (8.5 FL OZ)



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67860-318
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:67860-318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/07/2016	
2	NDC:67860-318-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/07/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/07/2016	

Labeler - Cariba International (049354067)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(67860-318)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(67860-318)

Revised: 4/2022

Cariba International