ANTISEPTIC MOUTHRINSE- 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.

Spring Mint Antiseptic Mouthrinse 072.003/072AL

Active ingredients

Eucalyptol 0.092%, Menthol 0.042%, Methyl sailcylate 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 incresed 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 rednss 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

• do not swallow - not intended to replace brushing or flossing

adults and and children 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonful) between teeth twice a day for 30 seconds then spit out children under 12 years of age - consult a dentist or doctor

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 21.6 %, sorbitol solution, poloxamer 407, benzoic acid, sodium saccharin, flavor, sodium citrate, D&C yellow no. 10, FD7C green no.3

Distributed by:

Cariba International

P.O. Box 1208

Safety Harbor, Florida 34695

MADE IN USA WITH US AND FOREIGN COMPONENTS

Principal display panel

Sealed with Printed Neckband for your Protection

CARIBA CARE

ANTISEPTIC

Mouthwash

ANTIGINGIVITIS/ANTIPLAQUE

FRESH MINT

Kills germs that cause bad breath, plaque & the gum disease gingivitis

250 mL (8.5 FL OZ)



ANTISEPTIC MOUTHRINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product	Inform	ation
Product	Intorm	ation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67860-072
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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: O414PZ 4LPZ)	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)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
BENZOIC ACID (UNII: 85KN0B0MIM)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:67860- 072-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/18/2016	
	2	NDC:67860- 072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/18/2016	

Marketing Information			
Marketing Category			Marketing End Date
OTC monograph not final	part348	11/18/2016	

Labeler - Cariba International (049354067)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(67860-072)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(67860-072)

Revised: 1/2023 Cariba International