ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash H-E-B

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.

HEB Antiseptic Mouthrinse 664.003 664AU

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, antiplaque

Use

help 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

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 (59° - 77°F).

Inactive ingredients

water, alcohol (21.6%), sorbitol solution, flavor, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, FD&C green no. 3

Questions?

Call 1-888-593-0593

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION.

The ADA Council on Scientific Affairs Acceptance of HEB Cool Blue Mint Antiseptic Mouthwash is based on its finding that the product is effective in helping to prevent and reduce gingivitis and plaque above the gumline, when used as directed.

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

MADE WITH PRIDE AND CARE FOR H-E-B

San Antonio, TX 78204

Principal Display Panel

Compare to Listerine*

H-E-B COOL BLUE MINT ANTISEPTIC

ANTIGINGIVITIS/ANTIPLAQUE

MOUTHWASH

ADA Accepted American Dental Association

- Helps Fight Germs That Causes Bad Breath
- Fights Plague & Gingivitis

50.7 FL OZ (1.58 QT) 1.5 L



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:37808-664

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
		0.42

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	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)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
BENZOIC ACID (UNII: 8SKN0B0MIM)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:37808- 664-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/19/2009		
2	NDC:37808- 664-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/19/2009		
3	NDC:37808- 664-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/19/2009		
4	NDC:37808- 664-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/19/2009		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/19/2009	

Labeler - H-E-B (007924756)

Registrant - Vi-Jon (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		790752542	manufacture(37808-664)	

Establishment				
Name	Address	ID/FEI	Business Operations	

Vi-Jon	088520668	manufacture(37808-664)
VI-JOII	000320000	manaractare(57000-004)

Revised: 6/2022 H-E-B