ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Demoulas Super Markets, 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.

Market Basket 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

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 unmder 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 21.6%, sorbitol, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, flavor, FD&C green no.3

ADA Council Statement

The ADA Council on Scientific Affairs Acceptanc of Market Basket Blue Mint Antiseptic mouth rinse is based on its finding that the product is effective in helping to prevent and reduce gingivitis and plque above the gumline, when used as directed

Disclaimer

This product is not manufactured or distribted by Johnson & Johnson Healthcare Products, distributor of Listerine

Adverse Reactions

DISTRIBUTED BY
DEMOULAS SUPER MARKETS, INC
875 EAST STREET
TEWKSBURY, MA 01876
MADE IN THE U.S.A.

principal display panel

MORE FOR YOUR DOLLAR
MARKET BASKET
Compare to Listerine
ANTISEPTIC
MOUTH RINSE

Blue Mint

Kills germs that cause Bad Breath, Plaque and the gum disease Gingivitis

ADA

Accepted

American

Dental

Association

Sealed With Printed Neckband For Your Protection

1 L (33.8 FL OZ)



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:53942-664 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	
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)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
BENZOIC ACID (UNII: 85KN0B0MIM)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			

Packaging				
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:53942- 664-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/1998	
:	NDC:53942- 664-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/1998	
	NDC:53942- 664-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2022	

Marketing Information			
keting End Date	Marketing Start Date	Marketing Application Number or Monograph Category Citation	
	03/15/1998	part356	OTC monograph not final
	03/15/1998	part356	

Labeler - Demoulas Super Markets, Inc (007869647)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(53942-664)	

Establishment					
Name	Address	ID/FEI	Business Operations		
Vi-Jon, LLC		088520668	manufacture(53942-664)		

Revised: 3/2022 Demoulas Super Markets, Inc