ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash Demoulas Super Markets

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 rev 2-AN

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 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 you 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. It antiseptic properties are not affected. Store at room temperature (59° - 77° F)

Inactive ingredients

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

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

DISTRIBUTED BY:

DEMOULAS SUPER MARKETS, INC.

875 EAST STREET, TEWKSBURY, MA 01876

principal display panel

"MORE FOR YOUR DOLLAR"

MARKET BASKET

COMARE TO LISTERINE*

ANTISEPTIC

MOUTH RINSE

Fresh Mint

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

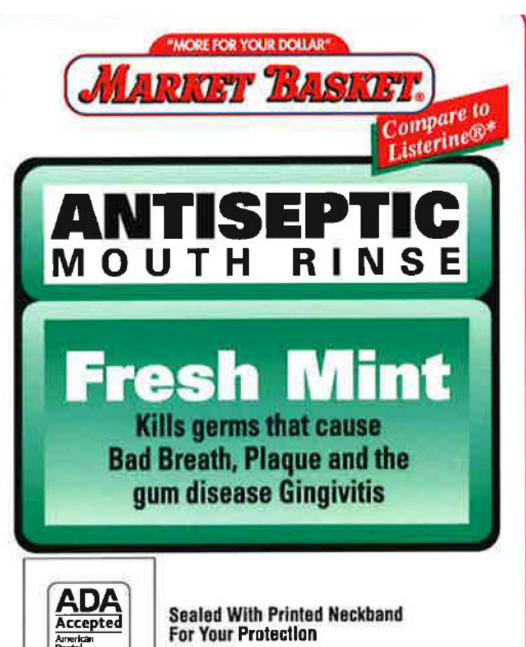
ADA Accepted

American Dental Association

- Helps reduce plaque
- Helps reduce gingivitis

Sealed With Printed Neckband For Your Protection

500 mL (16.9 FL OZ)





- Helps reduce plaque
- Helps reduce gingivitis

500 mL (16.9 FL OZ)

L0001463FD

ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53942-072

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 SOLUTION (UNII: 8KW3E207O2)				
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)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53942- 072-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	
2	NDC:53942- 072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	
3	NDC:53942- 072-13	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	
4	NDC:53942- 072-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/30/2007	

Labeler - Demoulas Super Markets (007869647)

Registrant - Vi Jon, LLC (790752542)

EstablishmentNameAddressID/FEIBusiness OperationsVi Jon, LLC790752542manufacture(53942-072)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi Jon, LLC		088520668	manufacture(53942-072)	

Revised: 1/2023 Demoulas Super Markets