

ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Western Family Foods, 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.

Drug Facts

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 year 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 solution, poloxamer 407, benzoic acid, flavoring, sodium saccharin, sodium citrate, citric acid, D+C yellow no. 10,

FD+C green no.3

claims

Sealed With Printed Neckband For Your Protection

The ADA Council on Scientific Affairs Acceptance of Western Family Spring Mint Antiseptic Mouth Rinse is based on its finding of 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

DSP-TN-15000

DSP-MP-34

SDS-TN-15012

principal display panel

WESTERN

FAMILY

ANTISEPTIC

Mouth Rinse

Kills Germs that
cause Bad breath,

Plaque + the gum
disease Gingivitis

Spring Mint

ADA

Accepted

American

Dental

Association

33.8 FL OZ

(1 QT 1.8 FL OZ)

1L



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-072
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: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)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	

BENZOIC ACID (UNII: 8SKN0B0MM)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/14/1995	
2	NDC:55312-072-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/14/1995	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/14/1995	

Labeler - Western Family Foods, Inc. (192166072)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(55312-072)