

ANITSEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Pharmacy Value Alliance LLC

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 072.003/072AL rev 2

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose section

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

Questions?

1-888-593-0593

ADA Statement

"The ADA Council on Scientific Affairs' Acceptance of Premier Value Sprint Mint Mouth Rinse 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."

Disclaimer

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

Adverse Reactions Section

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Distributed by:

Pharmacy Value Alliance LLC

407 East Lancaster Avenue,

Wayne, PA 19087

www.emersongroup.com

072.002/072AL

principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

COPARE TO FRESHBURST LISTERINE ANTISEPTIC MOUTHWASH

Premier

Value

Antiseptic

Mouthrinse

Antigingivitis/Antiplaque

spring mint

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

ADA
 Accepted
 American
 Dental
 Association
 1 L (33.8 FL OZ)



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-941
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: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
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:68016-941-77	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/19/2003	

Labeler - Pharmacy Value Alliance LLC (101668460)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(68016-941)