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.

Spring Mint Antiseptic Mouthrinse 072.003/072AL rev2-AN

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

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

If for any reason you are not satisified 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

principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

COMPARE TO FRESHBURST LISTERINE ANTISEPTIC MOUTHWASH*

Premier Value

Antiseptic Mouthrinse

Antigingivitis/Antiplaque

spring mint

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

1 L (33.8 FL OZ)



ANITSEPTIC 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 Basis of Ingredient Name Strength Strength 0.92 mg EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK) **EUCALYPTOL** in 1 mL 0.42 ma MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL in 1 mL METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID -0.60 mg ALTINI CALICVIATE

UNII:O414PZ4LPZ)	METHIL SALICILATE	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)				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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, LLC (790752542)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(68016-941)

Revised: 1/2023 Pharmacy Value Alliance LLC