ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash CVS Pharmacy, 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.

CVS 318.003 - 318AI

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 your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist

gingivitis, bleeding, or redness persists for more than 2 weeks

Keep out of reach of chrildren

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 twice a day 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 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

Disclaimer

This product is manufactued or distributed by Johnson & Johnson Healthcare Products, distributor of Original Listerine Antiseptic Mouthwash

Adverse reactions

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 318.003/318AH 2019 CVS/pharmacy CVS.com 1-800-SHOPCVS Made in the U.S.A. of U.S. and oreign components V-16224 CVS Quality Money Back Guarantee DSP-TN-15000 DSP--MO-34 SDS-TN-15012

principal display panel

Compare to the active ingredients in Listerine Original Antiseptic

CVS

Health

Antiseptic

Mouthwash

ANTIGINGIVITIS/ANTPLAQUE

Kills gemrs that cause plaque, gingivitis & bad breath

Original

ADA

Accepted

American

Dental

Association

- Helps reduce plaque
- Helps reduce gingivitis

Sealed with printed neckband for your protection.

Do not use if broken or missing

1L (33.8 FL OZ)



Compare to the active ingredients in Listerine® Original Antiseptic*

Antiseptic Mouthwash

Kills germs that cause plaque, gingivitis & bad breath

Original



Helps reduce plaque
Helps reduce gingivitis

Sealed with printed neckband for your protection, Do not use if broken or missing.

250 mL (8.5 FL OZ)

ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-898
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:0414PZ4LPZ)	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)		
BENZOIC ACID (UNII: 85KN0B0MIM)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
CARAMEL (UNII: T9D99G2B1R)		

Packaging

7	# Item	n Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:5 898-8	59779- 6	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2009	
:	2 NDC:5 898-6	59779- 9	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2009	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part356	05/12/2009	

Labeler - CVS Pharmacy, Inc (062312574)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(59779-898)
Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(59779-898)

Revised: 9/2023

CVS Pharmacy, Inc