ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Shopko Operating Co., 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.

Antiseptic Mouthrinse 318.003/318AH-AI

TEP

Sealed with printed neckband for your protection

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 imediately. 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 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

Disclaimer

This product is not manufactured or distributed by Johnson & Johnmson Healthcare Products, distributor of Original Listerine

Adverse Reaction

Manufactured by Vi-Jon, Inc.,

One Swan Dr., Smyrna TN 37167

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www. shopko.com

For consumer questions

call 1-888-593 0593

principal display panel

Shopko

COMPARE TO THE ACTIVE INGREDIENTS OF LISTERINE

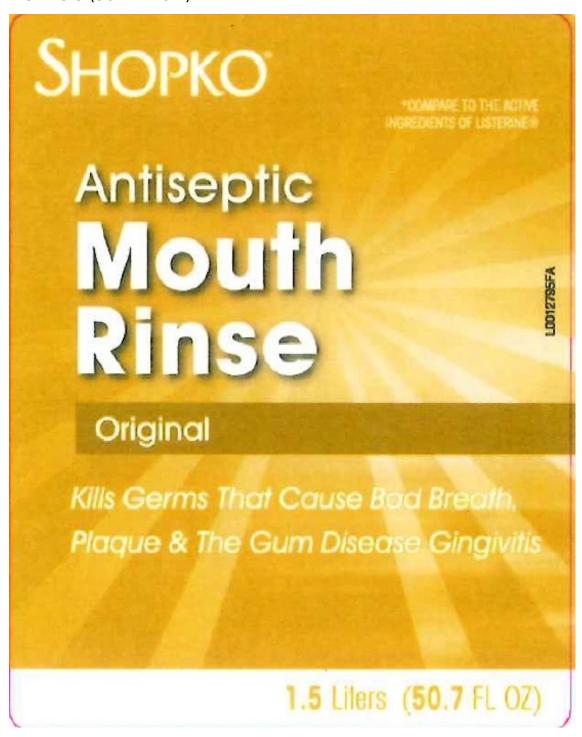
Antiseptic

Mouth

Rinse

Original

Kills Germs That Cause Bad Breath, Plaque & The Gum Disease Gingivitis 1.5 Liters (50.7 FL OZ)



ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-318	
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)		
BENZOIC ACID (UNII: 85KN0B0MIM)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
CARAMEL (UNII: T9D99G2B1R)		

Packaging						
# Item Code		Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37012- 318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/09/1991			
	NDC:37012- 318-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/09/1991			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing Category Citation Date Date				
OTC monograph not final	part356	01/09/1991		

Labeler - Shopko Operating Co., LLC (023252638)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(37012-318)	

Establishme	nt		
Name	Address	ID/FEI	Business Operations

Vi-Jon, LLC	088520668	manufacture(37012-318)	
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Revised: 6/2023 Shopko Operating Co., LLC