

ANTISEPTIC - eucalyptol, menthol, methyl salicylate, thymol rinse
DZA Brands, 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

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 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 & Johnson Healthcare Products, distributor of Listerine

Adverse reactions

Distributed by: DZA Brands, LLC

2110 Executive Drive

Salisbury, NC 28147

For product questions or concerns contact us at 1-866-322-2439. Please include UPC number and code from the package

Principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

healthy

accents

original flavor

antiseptic

mouth rinse

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

compare to the active

ingredients of Listerine

1 L (33.8 FL OZ)

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10003679K

ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-318
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: 8SKN0B0MIM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2008	
2	NDC:55316-318-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2008	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/05/2008	

Labeler - DZA Brands, LLC (090322194)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55316-318)

Establishment

Name	Address	ID/FEI	Business Operations
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Vi-Jon, LLC

088520668

manufacture(55316-318)

Revised: 6/2023

DZA Brands, LLC