

**ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash**  
**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.*

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**Drug Facts**

**Active ingredients**

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Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

**Purpose**

Antigingivitis, antiplaque

**Use**

help 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 between teeth for 30 seconds then spit out

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 benzoate, FD&C green no.3

**Disclaimer**

This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor 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 package

664.001/664AS

**Package Label**

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

healthy

accents

blue mint

antiseptic

mouth rinse

kills germs that cause bad breath,

plaque & the gum disease gingivitis

compare to the active

ingredients of Listerine

1L (33.8 FL OZ)

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healthy accents™

blue mint  
**antiseptic  
mouth rinse**

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1 L (33.8 FL OZ)

L00030461C

## ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55316-664
<b>Route of Administration</b>	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: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	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: 8SKN0B0MM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-664-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2008	
2	NDC:55316-664-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2008	
3	NDC:55316-664-69	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 (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(55316-664)