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.

Healthy Accents 664.003 664AU

Active ingredients

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

principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

healty

accents

blue mint

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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blue mint 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 0Z)

1000304510

ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-664	
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	

	Stiength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	

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#	ltem 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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC managraph pat	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(55316-664)	

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55316-664)

Revised: 5/2022

DZA Brands LLC