ANTISPETIC- eucalyptol, menthol, methyl salicylate and 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.

Drug Facts

Active ingredients

Active ingredients

Eucalyptol 0.0692%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

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Antigingivitis, antiplaque

Use

Use help control plaque that leads to gingivitis

Warnings

Warnings

Do not use

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

Stop use and ask a dentist if gingivitis, bleeding, or redness persists for more than 2 weeks.

Keep out of reach of children.

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

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 unmder 12 years of age - consult a dentist or doctor

• this rinse is not intended to replace brushing or flossing

Other information

Other informationcold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59°-77°F)

Inactive ingredients

Inactive ingredients water, alcohol 21.6%, sorbitol solution, flavor, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, FD+C green no.3

Dis claimer

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 package

Principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

healthy

accents

blue mint

antiseptic

mouth rinse

kills germs that cause bad breath,

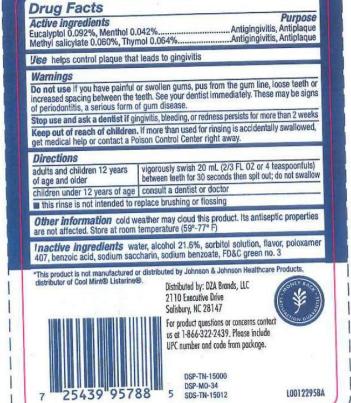
plaque + the gum disease gingivitis

compare to the active

ingredients of Listerine

500 mL (16.9 FL OZ)





ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55316-664
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EUCALYPTOL (EUCALYPTOL)	EUCALYPTOL	0.92 mg in 1 mL	
MENTHOL (MENTHOL)	MENTHOL	0.42 mg in 1 mL	
METHYL SALICYLATE (SALICYLIC ACID)	METHYL SALICYLATE	0.60 mg in 1 mL	
THYMOL (THYMOL)	THYMOL	0.64 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER			
ALCOHOL			
SORBITOL			
POLOXAMER 407			
BENZOIC ACID			
SACCHARIN SO DIUM			
SO DIUM BENZO ATE			

FD&C GREEN NO. 3

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-664-77	500 mL in 1 BOTTLE, PLASTIC		
2	NDC:55316-664-86	1000 mL in 1 BOTTLE, PLASTIC		

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)	

Revised: 2/2013 DZA Brands LLC