MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash DOLGENCORP,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 318.003/318AH

Active ingredient

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 is 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 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\(\text{I}\)-77\(\text{I}\)F)

Inactive ingredients

water, alcohol 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

TEP

Sealed With Printed Neckband For Your Protection

disclaimer

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

Adverse reactions

DISTRIBUTED BY OLD EAST MAIN CO. 100 MISSION RIDGE GOODLETTSVILLE, TN 37072

100%

Quality

Guaranteed

If you're not satisfied wit this product for any reason, please call us so we can make ou 100% satisfied. (888)309-9030

PRINCIPAL DISPLAY PANEL

DG| health

Compare to

Original Listerine

Antiseptic Mouthwash

ANTISEPTIC

MOUTHWASH

Antigingivitis/Antiplaque

AMBER

KILLS 99.9% OF

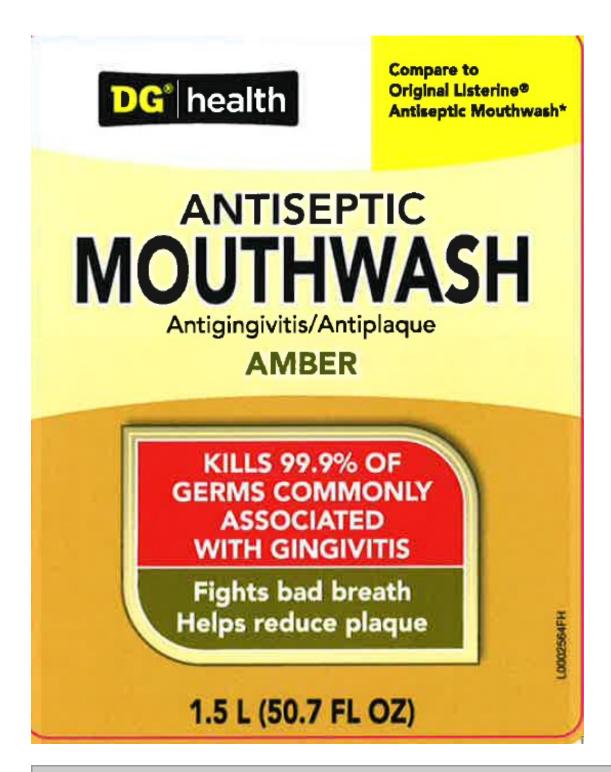
GERMS COMMONLY

ASSOCIATED WITH GINGIVITIS

Fights bad breath

Helps reduce plaque

1.5 L (50.7 FL OZ)



MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Pro	duct	Info	rmatio	n

Product Type HUMAN OTC DRUG Item Code (Source) NDC:559 10-318

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	EUCAL YPTOL (UNII: RV616604TK) (EUCAL YPTOL - UNII: RV616604TK)	EUCAL YPTOL	0.92 mg in 1 mI.

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: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E)	THYMOL	0.64 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
CARAMEL (UNII: T9D99G2B1R)				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:55910-318- 12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/11/20 0 1	
	2	NDC:55910-318- 77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/11/20 0 1	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	0 1/11/20 0 1	

Labeler - DOLGENCORP,LLC (068331990)

Registrant - Vi-Jon (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		790752542	manufacture(55910-318)	

Revised: 5/2020 DOLGENCORP,LLC