ANTISPETIC- 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

TEP

Sealed With Printed Neckband for your protection

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 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) 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 of Cool Mint Listerine Antiseptic Mouthwash

DSP-TN-15000 DSP-MO-34 SDS-TN-15012 100% Satisfaction Guaranteed If you're not satisfied with this product for any reason, please call us so we can make you 100% satisfied (888)309-9030

Adverse Reactions

DISTRIBUTED BY DOLGENCORP, LLC 100 MISSION RIDGE GOODLETTSVILLE, TN 37072 664.002/664AS

principal display panel

DG|health Compae to Cool Mint Listerine Antiseptic Mouthwash ANTISEPTIC MOUTHWASH ANTGINGIVITIS/ANTIPLAQUE BLUE MINT Kills germs that cause bad breath, plaque and the gum disease gingivitis 1.5 L (50.7 FL OZ)



Compare to Cool Mint[®] Listerine[®] Antiseptic Mouthwash*

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1.5 L (50.7 FL OZ)

ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Sou	rce)	NDC:55	5910-664
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name		Basis of Stren	ıgth	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)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)			
SACCHARIN SO DIUM (UNII: SB8ZUX40TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			

Packaging

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# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55910-664- 77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/1994	
2 NDC:55910-664- 12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/1994	
3 NDC:55910-664- 69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/1994	
4 NDC:55910-664- 19	94 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/1994	

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not finalpat35607/29/199407/29/1994

Labeler - Dolgencorp, llc (068331990)

Registrant - Vi-Jon (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		790752542	manufacture (55910-664)	

Revised: 5/2019

Dolgencorp, llc