ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Save A Lot Food Stores LTD

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 being well 664

Active ingredients

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 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°-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

TEP

SEALED WITH PRINTED NECK BAND FOR YOUR PROTECTION

Adverse Reactions

DISTRIBUTED BY: SAVE-A-LOT FOOD STORES, LTD.

ST ANN, MO 63074 savealot.com

100% MONEY BACK GUARANTEE

principal display panel

NDC 46994-664-86

being well

COMPARE TO COOL MINT LISTERINE ANTISEPTIC MOUTHWASH

Antiseptic

Mouthrinse

Antigingivitis/Antiplaque

BLUE MINT

ADA

Accepted

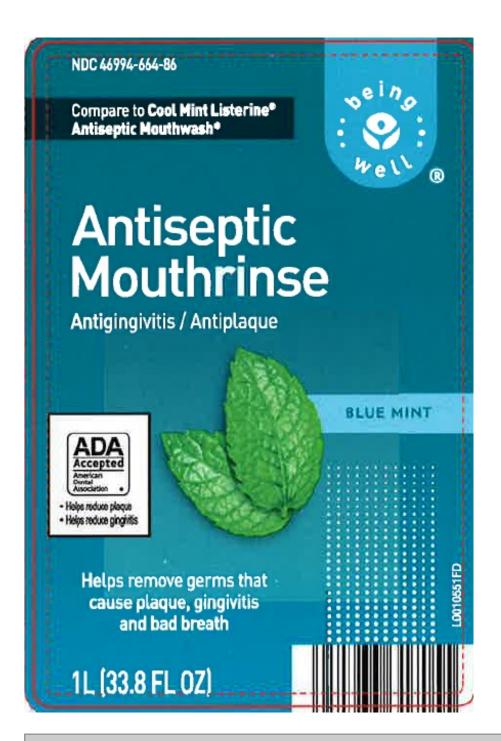
Amterican

Dental

Association

- Helps reduce plaque
- Helps reduce gingivitis
- Helps remove germs that cause plaque, gingivitis and bad breath

1L (33.8 FL OZ)



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46994-664
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	$0.64 \ mg \ in \ 1 \ mL$
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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 SODIUM (UNII: SB8ZUX40TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:46994-664- 86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/17/2010	

Labeler - Save A Lot Food Stores LTD (095484572)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(46994-664)

Revised: 4/2020 Save A Lot Food Stores LTD