## ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Cardinal Health, 110 dba Leader

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.

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#### Leader 664.003 664AU

#### **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. Poison Control Center 1-800-222-1222 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, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, Flavor, green 3

#### disclaimer

This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine registered trademark of Listerine Cool Mint.

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100% Money Back Guarantee

Return to place of purchase if not satisfied.

DISTRBUTED BY CARDINAL HEALTH

DUBLIN, OHIO, 43017

www.myleader.com

1-800-200-6313

#### principal display panel

LEADER

NDC 70000-0528-1

**Antiseptic** 

Mothrinse

Antigingivitis/Antiplaque

Blue Mint

Kills Germs That Cause:

**Bad Breath** 

Plaque

Gingivitis Gum Disease

**COMPARE TO** 

LISTERINE

COOL MINT

active ingredients

100% Money

Back Guarantee

500 mL (16.9 FL OZ)

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION



NDC 70000-0528-1

**Antiseptic** 

# Mouthrinse

Antigingivitis / Antiplaque

L0000000FX

## Blue Mint

Kills Germs That Cause: Bad Breath Plaque Gingivitis Gum Disease COMPARE TO LISTERINE®
COOL MINT active ingredient

100% Money Back Guarantee

500 mL (16.9 FL OZ)

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

#### **ANTISEPTIC**

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0528
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: 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: 85KN0B0MIM)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l		NDC:70000- 0528-1	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/1997	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/15/1997	

### Labeler - Cardinal Health, 110 dba Leader (063997360)