# ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash Marc Glassman, Inc

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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### **Drug Facts**

# **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 chrildren

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 twice a day 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 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

#### Disclaimer

This product is not manufactued or distributed by Johnson & Johnson Healthcare Products, distributor of Original Listerine Antiseptic Mouthwash.

#### Adverse reaction

Distributed by:

Marc Glassman, Inc.

West 130th Street

Cleveland, OH 44130

318.003/318AH

## Principal display panel

NDC 68998-318-12

Compare to Original Listerine Mouthwash

Marck's

Fresh Savings Smart Living

antseptic

Mouthwash

#### HELPS IMPROVE ORAL HYGIENE

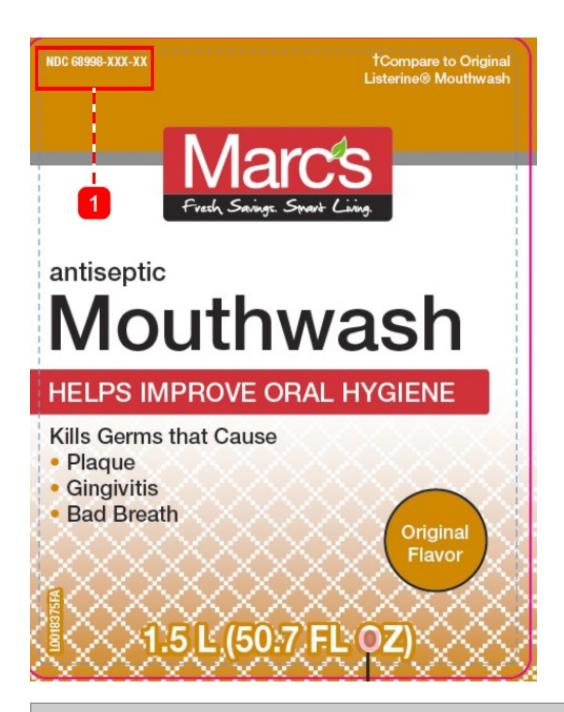
Kills Germs that Cause

- Plaque
- Gingivitis
- Bad Breath

Original

Flavor

1.5 L (50.7 FL OZ)



#### ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-318	
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: 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:68998-318- 12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 4/15/20 19	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	04/15/2019		

# Labeler - Marc Glassman, Inc (094487477)

# **Registrant -** Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(68998-318)

Revised: 4/2019 Marc Glassman, Inc