

MOUTHWASH- menthol, methyl salicylate, thymol liquid
Orazen 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.

Active ingredients

EUCALYPTOL 0.092%, MENTHOL 0.042%, METHYL SALICYLATE 0.060%, THYMOL 0.064%

Purpose

Antigingivitis, Antiplaque

Uses

Helps reduce plaque that leads to

- gingivitis
- bleeding gums

Warnings

Stop use and see your dentist immediately if

- gingivitis, bleeding or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth, or increasing space between the teeth

These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age . If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

adult and children 12 years of age and older	vigorously swish 20 milliliters of rinse between teeth twice a day for 30 seconds then spit out. Do not swallow the rinse.
children 6 to 20 years of age	supervise use
children under 6 years of age	do not use

Other information

- not intended to replace brushing or flossing
- store at room temperature (59-77F)
- cold weather may cloud this product, but will not affect its antiseptic properties.

Inactive ingredients

alcohol (21.6%), benzoic acid, flavor, green 3, poloxamer 407, sodium benzoate, sodium saccharin, sorbitol, water



DO NOT USE IF PRINTED BAND AROUND CAP IS BROKEN OR MISSING.
To open, squeeze cap and turn. To close, turn cap until it clicks.

Drug Facts	
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Use Helps reduce plaque that leads to • gingivitis • bleeding gums	
Warnings	
Stop use and see your dentist immediately if	
<ul style="list-style-type: none"> gingivitis, bleeding, or redness persists for more than 2 weeks you have painful or swollen gums, pus from the gum line, loose teeth, or increasing space between the teeth. 	
These may be signs or symptoms of periodontitis, a serious form of gum disease.	
Keep out of reach of children under 6 years of age.	
Distributed by: Lif Drug Store Products, Inc. 9300 Earhart Lane SW Cedar Rapids, IA 52404 1-877-507-6516 (M-F 8AM-4:30PM CST)	
Made in China LIFT PANEL FOR CONTINUED DRUG FACTS	

Drug Facts (continued)	
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*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Cool Mint® Listerine® Antiseptic Mouthwash.	

MOUThWASH

menthol, methyl salicylate, thymol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71927-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.6 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL
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

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-006-01	251 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/22/2019	

Labeler - Orazen Inc (080916640)

Revised: 4/2019

Orazen Inc