

**ANTISEPTIC BLUE MINT- eucalyptol, menthol, merthyl salicylate, thymol mouthwash
LIL' DRUG STORE PRODUCTS, 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.

Drug Facts

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.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Adults 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 12 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°F - 77°F)
- 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.

Label Copy



ANTISEPTIC BLUE MINT

eucalyptol, menthol, merthyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-5570
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: 059QF0K00R)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-5570-8	251 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/07/2019	

Labeler - LIL' DRUG STORE PRODUCTS, INC. (093103646)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(66715-5570)

Revised: 1/2019

LIL' DRUG STORE PRODUCTS, INC.