GIANT EAGLE ORIGINAL ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash

Apollo Health and Beauty Care 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

Antiplaque/Antigingivitis

Uses

helps reduce plaque that leads to

- gingivitis
- bleeding gums

Warnings

Stop use and ask a dentist 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 spacing 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

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

Other information

- this rinse is not intended to replace brushing or flossing
- store at room temperature. Cold weather may cloud this product, its antiseptic properties are not affected

Inactive ingredients

Water (Aqua), Alcohol (26.9%), Benzoic Acid, Poloxamer 407, Sodium Benzoate, Caramel.

Label copy



Drug Facts		TO OPEN: squeeze cap and turn. To close, turn cap until
Active Ingredients Eucalyptol 0.092% Menthol 0.042% Methyl Salicylate 0.060% Thymol 0.064%	Purpo Antiplaque/Antigin	it clicks. Do not use if printed band around cap is broken or missing.
Uses helps reduce plaque that leads to ■ gingivit	tis ■bl eeding gums	— COOLBOOST™
Warnings Stop use and ask a dentist if ■ gingivitis, for more than 2 weeks. ■ You have painful or swallen g loose teeth, or increasing spacing between the teeth. Their of periodonthits, a serious form of gum disease. Keep out of reach of children under 6 years of age. If accidentally swallowed, get medical help or contact a Poiso	ums, pus from the gun se may be signs or sym more than used for rins	n line, ploms CoolBoost™ technology! CoolBoost™ technology provides a consistent and long lasting cooling effect that continues
Directions Adults and children 12 years of age a 20 milliters of rinse between your teeth twice a day fo out. Do not swallow the rinse, Children 6 years to un supervise use. Children under 6 years of age: do no	r 30 seconds and then der 12 years of age:	swish drink. The best part? Your cool fresh breath will become cleaner as you reduce plaque and kill germs with every use!
Other Information This rinse is not inten- lossing. Store at room temperature. Cold weather antiseptic properties are not affected.	nded to replace brush may cloud this produ	CoolBoost™ is a Registered Ing or Trademark of Apollo Health & Beauty Care, Inc.
Inactive Ingredients Water (Aqua), Alcoh Poloxamer 407, Sodium Benzoate, CarameL	nol (26.9%), Benzoic A	Acid, No animal testing
DISTRIBUTED BY GIANT EAGLE, INC., PITTSBURGH, PA 15238-2809 9 2019 GIANT FAGLE, INC. DUESTIONS? COMMENTS? CALL 1-800-553-2324 GIANTEGIG, COM ANDE IN CANADA This product is not manufactured or distributed by	ov Johnson & Johns	
This product is not manufactured or distributed be lealthcare products, distributor of Listerine®. IOO% satisfaction or double your money back.	06-24300	0 30034 93601

GIANT EAGLE ORIGINAL ANTISEPTIC

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-018
Route of Administration	ORAL		

100% satisfaction or double your money back.

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)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63148-018-	$1000\ mL$ in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/11/2019	
Marketing Ir	nformation		
Marketing Categ	gory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not	final part356	09/11/2019	

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

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-018)	

Revised: 9/2019 Apollo Health and Beauty Care Inc.