

**GIANT EAGLE WINTERMINT WITH FLUORIDE- sodium fluoride 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.*

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**Drug Facts**

**Active ingredient**

Sodium Fluoride 0.02% (0.01% w/v Fluoride ion)

**Purpose**

Anticavity

**Uses**

aids in the prevention of dental cavities or decay

**Warnings**

**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 6 years of age and older: use twice a day after brushing your teeth with a toothpaste. Vigorously swish 10 mL of rinse between your teeth for 1 minute then spit out. Do not swallow the rinse. Do not eat or drink for 30 mins after rinsing.
- Instruct children 12 years of age in good rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 6 years of age: Consult a dentist or doctor.

**Other information**

- Cold weather may cloud this product, but will not affect its anticavity properties.
- Store at room temperature.

**Inactive ingredients**

Water (Aqua), Alcohol (21.6%), Sorbitol, Poloxamer 407, Sodium Lauryl Sulfate, Eucalyptol, Flavor, Methyl Salicylate, Thymol, Phosphoric Acid, Sucralose, Menthol, Disodium Phosphate, Red 40 (CI 16035), Blue 1 (CI 42090).

**Label copy**



**Drug Facts**

<b>Active Ingredient</b> Sodium Fluoride 0.02% (0.01% w/v Fluoride ion)	<b>Purpose</b> Anticavity
<b>Uses</b> aids in the prevention of dental cavities or decay	
<b>Warnings</b> 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.	
<b>Directions</b> Adults and children 6 years of age and older: use twice a day after brushing your teeth with a toothpaste. Vigorously swish 10 mL of rinse between your teeth for 1 minute then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.	
<b>Other Information</b> Cold weather may cloud this product, but will not affect its anticavity properties. Store at room temperature.	
<b>Inactive Ingredients</b> WATER (AQUA), ALCOHOL (21.6%), SORBITOL, POLOXAMER 407, SODIUM LAURYL SULFATE, EUCALYPTOL, FLAVOR, METHYL SALICYLATE, THYMOL, PHOSPHORIC ACID, SUCRALOSE, MENTHOL, DISODIUM PHOSPHATE, RED 40 (CI 16035), BLUE 1 (CI 42090).	

DISTRIBUTED BY GIANT EAGLE, INC., PITTSBURGH, PA 15238-2809  
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100% satisfaction or double your money back.  
06-24338

**TO OPEN:** squeeze cap and turn. To close, turn cap until it clicks. Do not use if printed band around cap is broken or missing.

**COOLBOOST™ TECHNOLOGY**

Fight plaque and kill odor causing germs while experiencing the cool freshness of CoolBoost™ technology! CoolBoost™ technology provides a consistent and long lasting cooling effect that continues to work long after use – for up to 3 hours, without affecting the taste of food or drink. The best part? Your cool fresh breath will become cleaner as you reduce plaque and kill germs with every use!

CoolBoost™ is a Registered Trademark of Apollo Health & Beauty Care, Inc.

\*This product is not manufactured or distributed by Johnson & Johnson Healthcare products, distributor of Listerine®.

No animal testing

**GIANT EAGLE WINTERMINT WITH FLUORIDE**  
sodium fluoride mouthwash

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63148-021
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EUCALYPTOL (UNII: RV6J6604TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
THYMOL (UNII: 3J50XA376E)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 94255I6E2T)	
FD&C RED NO. 40 (UNII: WZB9127X0A)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-021-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/21/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/21/2019	

**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(63148-021)

Revised: 10/2019

Apollo Health and Beauty Care Inc.