HYVEE ANTISEPTIC BLUE MINT- eucalyptol, menthol, methyl salicylate, thymol liquid HYVEE 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

TO HELP REDUCE AND PREVENT

- PLAQUE
- GINGIVITIS

WARNINGS

DO NOT USE FOR CHILDREN UNDER 12 YEARS OF AGE

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

- RINSE FULL STRENGTH FOR 30 SECONDS WITH 20 ML (2/3 FLUID OUNCE OR 4 TEASPOONFULS) MORNING AND NIGHT
- DO NOT SWALLOW

DIRECTIONS

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- DO NOT SWALLOW

OTHER INFORMATION

STORE AT ROOM TEMPERATURE. COLD WEATHER MAY CLOUD THIS PRODUCT. ITS ANTISEPTIC PROPERTIES ARE NOT AFFECTED

INACTIVE INGREDIENTS

WATER (AQUA), ALCOHOL (21.6%), SORBITOL SOLUTION, FLAVOR, POLOXAMER 407, BENZOIC ACID, SODIUM SACCHARIN, SODIUM BENZOATE, GREEN 3 (CI 42053)

QUESTIONS OR COMMENTS?

LABEL COPY



HYVEE ANTISEPTIC BLUE MINT

eucalyptol, menthol, methyl salicylate, thymol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-559	
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	0.6 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)				
SORBITOL (UNII: 506T60A25R)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				

SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:42507-559- 51	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/08/2015	

Labeler - HYVEE INC (006925671)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(42507-559)	

Revised: 4/2015 HYVEE INC