HYVEE ANTISEPTIC 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

OTHER INFORMATION

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

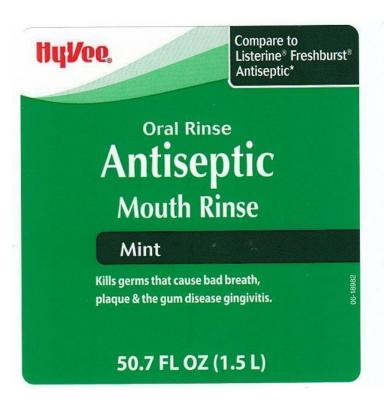
INACTIVE INGREDIENTS

WATER (AQUA), ALCOHOL (21.6%), SORBITOL, FLAVOR, POLOXAMER 407, BENZOIC ACID, SODIUM SACCHARIN, SODIUM BENZOATE, YELLOW 10 (CI 47005), GREEN 3 (CI 42053)

QUESTIONS OR COMMENT?

1-800-289-8343

LABEL COPY



Drug Facts	
Active ingredients Eucalyptol 0.092% Menthol 0.042% Methyl Salicylate 0.060% Thymol 0.064%	PurposeAntiplaque/Antigingivitis
Uses ■ To help reduce and prevent ■	plaque s gingivitis.
Warnings Do not use for children under 12 years	s of age.
Keep out of reach of children. ■ If swallowed, get medical help or contact a P	
Directions ■ Rinse full strength for 4 teaspoonfuls) morning and night. ■	30 seconds with 20 mL (2/3 fluid ounce o Do not swallow.
Other Information Store at roothis product. Its antiseptic properties a	om temperature. Cold weather may cloud are not affected.
Inactive ingredients: Water (Aqu Poloxamer 407, Benzoic Acid, Sodium Yellow 10 (CI 47005), Green 3 (CI 4205	Saccharin, Sodium Benzoate,
Questions or comments? 1-80	0-289-8343

DISTRIBUTED BY HY-VEE, INC. WEST DES MOINES, IA 50266

MADE IN CANADA SATISFACTION GUARANTEED CALL 1-800-289-8343 www.hy-vee.com DO NOT USE IF PRINTED BAND AROUND CAP IS BROKEN OR MISSING.

TO OPEN: SQUEEZE SMOOTH AREAS ON CAP AND TURN.
TO CLOSE: TURN CAP UNTIL IT LOCKS.

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HYVEE ANTISEPTIC MINT

eucalyptol, menthol, methyl salicylate, thymol liquid

 Product Information

 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:42507-560

 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: 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 SO DIUM (UNII: SB8 ZUX40 TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-560- 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(42507-560)	

Revised: 4/2015 HYVEE INC